### EXHIBIT D

## **Cynthia Bergmann**

# Reliance List in Addition to Materials Referenced in Report

**MDL** Wave 1

Case 2:12-md-02327 Document 2046-4 Filed 04/21/16 Page 3 of 37 PageID #: 39377 Bergmann, Cynthia - Materials List, updated 2.29.16.XLSX

Medical Literature

#### Description

(UITN) - Design of the Stress Incontinence Surgical Treatment Efficacy Trial (SISTEr) UROLOGY 66: 1213–1217, 2005

Abbott S. Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study. Am J Obstet Gynecol 2014; 210(2): 163.e1-163.e8.

Abdel-fattah M, Barrington JW, Arunkalaivanan AS. Pelvicol pubovaginal sling versus tension-free vaginal tape for treatment of urodynamic stress incontinence: a prospective randomized three-year follow-up study. Eur Urol 2004;46:629-35.

Abdel-fattah M, et al. (NHS Scotland) Primary and repeat surgical treatment for female pelvic organ prolapse and incontinence in parous women in the UK: a register linkage study. BMJ (2011)

Abdel-fattah M, et al. [Pop 341, 1 yr fu] Randomised prospective single-blinded study comparing 'inside-out' versus 'outside-in' transobturator tapes in the management of urodynamic stress incontinence: 1-year outcomes from the E-TOT study. BJOG 2010;117:870–878.

Abdel-Fattah M, et al. How common are tape erosions? A comparison of two versions of the transobturator tension-free vaginal tape procedure. BJU International (2006) 98, 594-598

Abdel-Fattah M, et al. Lower urinary tract injuries after transobturator tape insertion by different routes: a large retrospective study. BJOG 2006;113:1377–1381.

Abdel-Fattah M, et al. Prospective Randomised Controlled Trial of Transobturator Tapes in management of Urodynamic Stress Incontinence in Women: 3-Year Outcomes from the Evaluation of Transobturator Tapes Study. Euorpean Urology 62 (2012) 843-851

Abdel-Fattah M, et al. Single-Incision Mini-Slings versus Standard Midurethral Slings in Surgical Management of Female Stress Urinary Incontincen: A Meta-Analysis of Effectiveness and Complications. EUROPEAN UROLOGY 60 (2011) 468-480

Abdel-Fattah M. Evaluation of transobturator tapes (E-TOT) study: randomised prospective single-blinded study comparing inside-out vs. outside-in transobturator tapes in management of urodynamic stress incontinence: Short term outcomes. European Journal of Obstetrics & Gynecology and Reproductive Biology 149 (2010) 106-111

Abdel-Fattah, Familusi, Ramsay, N'Dow. A Randomised prospective single-blinded study comparing 'inside-out' versus 'outside-in' transobturator tapes in the management of urodynamic stress incontinence: 1-year outcomes from the E-TOT study. BJOG 2010;117:870–878.

Abdelwahab O, et al. Tension-free vaginal tape versus secure tension-free vaginal tape in treatment of female stress urinary incontinence. Curr Urol 2010; 4:93-98.

Abduljabbar H, et al. Comparison of the classic TVT and TVT Secur. Prime Research on Education ISSN: 2251-1253. Vol. 2(9), pp. 344-347, October 31st, 2012

ACOG & AUGS "Committee Opinion Number 603: Evaluation of Uncomplicated Stress Urinary Incontinence in Women Before Surgical Treatment", Obstet Gynecol. 2014 Jun;123(6):1403-7.

Adile B, et al. [ICS Abs. 550] [Pop 67, 3 yr fu] A Prospective Randomized study comparing Laparoscopic Burch vs. TVT-Short and Long term follow-up. (2003)

Agarwala N. A randomized comparison of two synthetic mid-urethral tension-free slings. UroToday International Journal, Vol 1, Iss 4, October 2008

Agostini A, et al. [Pop 12,280, 6 yr fu] Immediate Complications of Tension-Free Vaginal Tape (TVT): Results of a French Survey. European Journal of Obstetrics & Gynecology and Reproductive Biology 124 (2006) 237-239

Case 2:12-md-02327 Document 2046-4 Filed 04/21/16 Page 4 of 37 PageID #: 39378 Bergmann, Cynthia - Materials List, updated 2.29.16.XLSX Medical Literature

Aigmueller T, et al. Reasons for dissatisfaction ten years after TVT procedure. (2014) 25:213-217.

Aigmueller T, et al. Ten-year follow-up after the tension-free vaginal tape procedure. Am J Obstet Gynecol. 2011; 205:496.e1-5.

Albo, Richter, Kenton, Sirls, et al. (TOMUS 2 yr obj cure) [Pop 516, 24 mo fu] Treatment Success of Retropubic and Transobturator Mid Urethral Slings at 24 Months. The Journal of Urology, Vol. 188, 2281-2287, 2012.

Albo, Richter, Zimmern, Moalli, Sirls - Burch Colposuspension versus Fascial Sling to Reduce Urinary Stress Incontinence. N Engl J Med 2007; 356:2143-55.

Alcalay M, et al. Burch Colposuspension-A 10-20 year follow up. BJOG September 1995, Vol. 102, pp. 740-745

Alewijnse, D., et al - Effectiveness of pelvic floor muscle exercise therapy supplemented with a health ed. program to promote long-term adherence Among Women with Urinary Incontinence. Neurourology and Urodynamics, 22:284-295 (2003)

Amaro JL, et al. Clinical and quality-of-life outcomes after autologous fascial sling and tension-free vaginal tape: a prospective randomized trial. Int Braz J Urol 2009;35:60-66; discussion 66-67.

Amaro. AUA Abs 1460 A prospective randomized trial of autologous fascial sling (AFS) versus tension-free vaginal tape (TVT) for treatment of stress urinary incontinence. The Journal of Urology Vol. 177, No. 4, Suppl. Tuesday, May 22, 2007.

Amat I Tardiu L, Martinez Franco E, Lai'lla Vicens JM. Contasure-Needleless compared with transobturator-TVT for the treatment of stress urinary incontinence. Int Urogynecol J. 2011 Jul;22(7):827-833.

Amid. Biomaterials for abdominal wall hernia surgery and principles of their applications. Langenbecks Arch Chir (1994) 379:168-171

Amid. Classification of biomaterials and their related complications in abdominal wall hernia surgery. Hernia (1997) 1:15-21

Andonian S, Chen T, St-Denis B, Coreas J. Randomized clinical trial comparing suprapubic arch sling (SPARC) and tension-free vaginal tape (TVT): one-year results. Eur Urol 2005;47:537-541.

Andonian S, St-Denis B, Lemieux MC, Coreas J. Prospective clinical trial comparing Obtape® and DUPS to TVT: one-year safety and efficacy results. Eur Urol 2007;52:245-251.

Anger. Trends in the Surgical Management of Stress Urinary Incontinence among Female Medicare Beneficiaries. Urology. 2009 August; 74(2): 283–287

Angioli (2010) Eur Urol - Tension-free vaginal tape versus transobturator suburethral tape: five-year follow-up results of a prospective, randomised trial. Eur Urol. 2010 Nov;58(5):671-7

Angioli R, Plotti F, Muzii L, Montera R, Panici PB, Zullo MA. Tension-free vaginal tape versus transobturator suburethral tape: five-year follow-up results of a prospective, randomised trial. Eur Urol 2010; 58:671-677.

Aniuliene R. Tension-free vaginal tape versus tension-free vaginal tape obturator (inside-outside) in the surgical treatment of female stress urinary incontinence. Medicina (Kaunas). 2009;45(8):639-43.

Appell, R. et al. "Guideline for the Surgical Management of Female Stress Urinary Incontinence: 2009 Update", American Urological Association 2009. (2012)

Araco F, Gravante G, Sorge R, et al. TVT-O vs TVT: a randomized trial in patients with different degrees of urinary stress incontinence. Int Urogynecol J (2008) 19:917–926

Case 2:12-md-02327 Document 2046-4 Filed 04/21/16 Page 5 of 37 PageID #: 39379 Bergmann, Cynthia - Materials List, updated 2.29.16.XLSX Medical Literature

Arunkalaivanan, AS, Barrington, JW. Randomized trial of porcine dermal sling Pelvicol implant vs TVT in the surgical treatment of stress incontinence: a questionnaire-based study. Int Urogynecol J (2003) 14:17-23

Athanasiou S, et al. Seven years objective and subjective outcomes of transobturator (TVT-O) vaginal tape: Why do tapes fail? Int Urogynecol J 2014; 25:219–225.

Athanasiou S. Grigoriadis T, Zacharakis D, Skampardonis N, Lourantou D, Antsaklis A. [Pop 124, 7 yr fu] Seven years of objective and sub-jective outcomes of transobturator (TVT-O) vaginal tape: why do tapes fail? Int Urogynecol J (2014) 25:219-225

Bai SW, Sohn WH, Chung DJ, Park JH, Kim SK. Comparison of the efficacy of Burch colposuspension, pubovaginal sling, and tension-free vaginal tape for stress urinary incontinence. Int J Gynaecol Obstet 2005;91:246-251.

Barber MD, et al. (TOT) [Pop 168, 24 mo fu] Transobturator tape compared with tension-free vaginal tape for the treatment of stress urinary incontinence: A randomized controlled trial. Obstet Gynecol 2008;111:611-621.

Barber MD, Weidner AC, Sokol Al, et al. Single-incision mini-sling compared with tension-free vaginal tape for the treatment of stress urinary incontinence: a randomized controlled trial. Obstet Gynecol 2012;119:328-337.

Barber. Cleveland Clinic leads multicenter trial of single-incision 'mini-sling' for stress urinary incontinence. The Cleveland Clinic Foundation 2011 Summer 2011

Barber. Comparison of 2 transvaginal surgical approaches and perioperative behavioral therapy for apical vaginal prolapse: The OPTIMAL Randomized Trial. (2014)

Barber. Sexual Function in women with urinary incontinence and Pelvic Organ Prolapse. Obstet Gynecol 2002;99:281-9

Barry [Pop 187, 3 mo fu] [TOT] A multi-centre, randomised clinical control trial comparing the retropubic (RP) approach versus the transobturator approach (TO) for tension-free, suburethral sling treatment of urodynamic stress incontinence: the TORP study. Int Urogynecol J (2008) 19:171-178

Basu M, Duckett J. A randomised trial of a retropubic tension-free vaginal tape versus a mini-sling for stress incontinence. BJOG 2010;117:730-735.

Beck. The Fascia Lata Sling Procedure for Treating Recurrent Genuine Stress Incontinence of Urine. Obstet Gynecol 72: 699, 1988)

Bemelmans. Are slings now the gold standard treatment for the management of female urinary stress incontinence and if so which technique? Current Opinion In Urology 2003, 13:301-307

Bent, Ostergard. GORE-TEX - Tissue reaction to expanded polytetrafluoroethylene suburethral sling for urinary incontinence: Clinical and histologic study. AM J OBSTET GYNECOL 1993;169:1198-204.

Bergman. [Pop 107 at 1 yr, 93 at 5 yr fu] Three surgical procedures for genuine stress incontinence. Five-year follow-up of a prospecitive randomized study. (1995)

Bernasconi F, et al.TVT SECUR System: Final results of a prospective, observational, multicentric study. Int Urogynecol J (2012) 23:93-98

Bezhenar (2013) [Pop 467. 7 yr] 7-Year old Clinical Experience of Treating women's urinary incontinence using suburethral slings, ICS Abs 768

Bianchi-Ferraro A, et al. Single-incision sling compared with transobturator sling for treating stress urinary incontinence: a randomized controlled trial. Int Urogynecol J (2012)

Black. [review + Hilton editorial] The effectiveness of surgery for stress incontinence in women: a systematic review. British Journal of Urology (1996),78,497-510

Case 2:12-md-02327 Document 2046-4 Filed 04/21/16 Page 6 of 37 PageID #: 39380 Bergmann, Cynthia - Materials List, updated 2.29.16.XLSX

Medical Literature

Blandon. Complications from vaginally placed mesh in pelvic reconstructive surgery. Int Urogynecol J (2009) 20:523 531

Bo K, Kvarstein B, Nygaard I. Lower urinary tract symptoms and pelvic floor muscle exercise adherence after 15 years. Obstet Gynecol 2005, 105(5 Pt 1):999-1005

Brito. Comparison of the efficacy and safety of surgical procedures utilizing autologous fascial and transobturator slings in patients with stress urinary incontinence. (2013)

Brubaker L, et al. [Pop 597, 24 mo fu] Adverse events over two years after retropubic or transobturator midurethral sling surgery: findings from the Trial of Midurethral Slings (TOMUS) study. Am J Obstet Gynecol 2011; 205:498.e1-6.

Brubaker, Richter, Zimmern. [Pop 482, 5 yr fu] 5-year Continence Rates, Satisfaction and Adverse Events of Burch Urethropexy and Fascial Sling Surgery for Urinary Incontinence. J Uro (2012) Vol. 187, 1324-1330

Bryans. Marlex gauze hammock sling operation with Cooper's ligament attachment in the management of recurrent urinary stress incontinence. Am. J. Obstet. Gynecol. 133: 292, 1979.

Burgio, Richter. Patient satisfaction with stress incontinence surgery. (2010)

But I, Faganelj M. Complications and short-term results of two different transobturator techniques for surgical treatment of women with urinary incontinence: a randomized study. Int Urogynecol J Pelvic Floor Dysfunct 2008;19:857-861.

Calvo. [Pop 92, 1 yr fu] Our experience with mini tapes (TVT-Secur and MiniArc) in the surgery for stress urinary incontinence. Acta Urol Esp. 2008; 32(10): 1013-1018

Cammu H, Van Nylen M, Blockeel C, Kaufman L, Amy JJ: Who will benefit from pelvic floor muscle training for stress urinary incontinence? Am J Obstet Gynecol 2004, 191(4):1152-1157

Cammu. Dramatic increase (1997-2007) in the number of procedures for stress urinary incontinence in Belgium. Int Urogynecol J (2010) 21:1511–1515

Campeau L, Tu LM, Lemieux MC, et al. A multicenter, prospective, randomized clinical trial comparing tension-free vaginal tape surgery and no treatment for the management of stress urinary incontinence in elderly women. Neurourol Urodyn 2007;26:990-994.

Carbone, Kavaler. Pubovaginal sling using cadaveric fascia and bone anchors; Disappointing early results. (2001)

Caruso S, Rugolo S, Bandiera S, Mirabella D, Cavallaro A, Cianci A. Clitoral blood flow changes after surgery for stress urinary incontinence: pilot study on TVT Versus TOT procedures. Urology 2007;70:554-557.

Celebi. [Pop 563, 5 yrs fu] Results of the tension-free vaginal tape procedure for treatment of female stress urinary incontinence: a 5-year follow-up study. Arch Gynecol Obstet (2009) 279:463–467

Chai, Richter, Kenton, Zimmern, Zyczynski (UITN) - Complications in Women Undergoing Burch Colposuspension Versus Autologous Rectus Fascial Sling for Stress Urinary Incontinence. (2009)

Chaliha, Stanton. Complications of surgery for genuine stress incontinence. British Journal of Obstefries and GYllaecology

December 1999, Vol 106, pp. 1238-1245

Chen (Zhong) - [Pop 187] Comparison of three kinds of midurethral slings for surgical treatment of female stress urinary incontinence. Urologia 2010; 77 (1): 37-42

Chene. [Pop 94, 5 yr fu] Long-term results of tension-free vaginal tape (TVT) for the treatment of female urinary stress incontinence. European Journal of Obstetrics & Gynecology and Reproductive Biology 134 (2007) 87–94

Case 2:12-md-02327 Document 2046-4 Filed 04/21/16 Page 7 of 37 PageID #: 39381 Bergmann, Cynthia - Materials List, updated 2.29.16.XLSX

Medical Literature

Cheng D, Caigang L. [Pop 103, 5 yr fu] Tension-free vaginal tape-obturator in the treatment of stress urinary incontinence: a prospective study with five-year follow-up. Eur J Obstet Gynecol Reprod Biol (2012) 161:228-231

Cho. Nationwide Database of Surgical Treatment (2014)

Cholhan H, et al. Dyspareunia association with paraurethral banding in the transobturator sling. Am J Obstet Gynecol 2010;202:481.e1-5.

Christensen. [Pop 169, median 7 yr fu] Long-term results of the Stamey bladder-neck suspension procedure and of the Burch Colposuspension. Scand J Urol Nephrol 31: 349- 353, 1997

Chughtai BI, et al. Midurethral Sling Is the Dominant Procedure for Female Stress Urinary Incontinence: Analysis of Case Logs from Certifying American Urologists. Urology (2013)

Chung. [Pop 91] Comparison of Laparoscopic Burch and Tension-Free Vaginal Tape in Treating Stress Urinary Incontinence in Obese Patients. JSLS (2002)6:17-21

Clark, Edwards (2003) Epidemiologic evaluation of reoperation for surgically treated pelvic organ prolapse and urinary incontinence

Clave. Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants. Int Urogynecol J (2010) 21:261–270

Clemons JL, et al. Impact of the 2011 FDA Transvaginal Mesh Safety Update on AUGS Members' Use of Synthetic Mesh and Biologic Grafts in Pelvic Reconstructive Surgery. Female Pelvic Medicine & Reconstructive Surgery, Volume 19, Number 4, July/August 2013.

Coady D. Chronic sexual pain. A layered guide to evaluation. Contemporary Ob/Gyn, September 2015, pp. 18-28.

Cobb, Kercher, Heniford. The Argument for lightweight Polypropylene Mesh in Hernia Repair. (2005)

Collinet P, et al. The safety of the inside-out transobturator approach for transvaginal tape (TVT-O) treatment in stress urinary incontinence: French registry data on 984 women. Int Urogynecol J (2008) 19:711–715

Colombo. [Pop 119] AIUG Proceedings (15th), Randomized Study to compare pereyra and TVT procedures for women with stress urinary incontinence and advanced urogenital prolapse. Urogynaecologia International Journal Vol. 19, No. 1 Jan-Apr 2005.

Constantini E, et al. [ICS Abs 3] Prolonged follow-up shows continence deter. after trans-obturator tape: Results from a randomised controlled study. (2013)

Cosson, M., et al. Mechanical properties of synthetic implants used in the repair of prolpase and urinary incontinence in women: Which is the ideal material? Int Urogynecol J (2003) 14:169-178

Costantini E, et al. [Pop 87, median 100 mos fu] Long-term efficacy of the trans-obturator and retropubic mid-urethral slings for stress urinary incontinence: update from a randomized clinical trial. World J Urol (2015)

Cox, A. et al. Reviews: Surgical Management of Female SUI: is there a gold standard? *Nat. Rev. Urol. 10, 78–89 (2013).* 

Cresswell. [pop 118, mean 6.6 yrs fu] Long-term evaluation of tension-free vaginal tape (TVT) outcomes for a UK surgeon: Objective assessment and patient satisfaction questionnaires. British Journal of Medical and Surgical Urology (2008) 1, 58—62

Darai E, et al. Functional Results After the Suburethral Sling Procedure for Urinary Stress Incontinence: A Prospective Randomized Multicentre Study Comparing the Retropubic and Transobturator Routes. EUROPEAN UROLOGY 51 (2007) 795-802

Case 2:12-md-02327 Document 2046-4 Filed 04/21/16 Page 8 of 37 PageID #: 39382 Bergmann, Cynthia - Materials List, updated 2.29.16.XLSX

Medical Literature

Davila GW, et al. Pelvic floor dsyfunction management practice patterns: A survey of members of the International Urogynecology Association. Int Urogynecol J (2002) 13:319-325

de Leval J, Thomas A, Waltregny D. The original versus a modified inside-out transobturator procedure: 1-year results of a prospective randomized trial. Int Urogynecol J 2011;22:145-156.

De Leval J. Novel SurgicalTechnique for theTreatment of Female Stress Urinary Incontinence:

Transobturator Vaginal Tape Inside-Out. Eur Urol. 2003 Dec;44(6):724-30

De Leval, J. The original versus a modified inside-out transobturator procedure: 1-year results of a prospective randomized trial. Int Urogynecol J (2011) 22:145–156

de Leval. (TVT-O \_inside-out\_ treatise) [Pop 107, 1 mo fu] Novel Surgical Technique for the Treatment of Female Stress Urinary Incontinence: Transobturator Vaginal Tape Inside-Out. (2003)

de Leval. [Pop 102, 1 yr fu] New Surgical Technique for Treatment of Stress Urinary Incontinence TVT-Obturator. New Developments. (2005)

de Oliveira L, Girao MJ, Sartori MG, Castro RA, Fonseca E. [Pop 85, med 14 mos fu] Abs 328 - Comparison of retro-pubic TVT, pre-pubic TVT and TVT transobturator in surgical treatment of women with stress urinary incontinence. Int Urogynecol J 2007;18 (Suppl I):S180-S181.

De Souza A, Dwyer PL, Rosamilia A, Hiscock R, Lim YN, Murray C, Thomas E, Conway C, Schierlitz L. Sexual function following retropubic TVT and transobturator Monarc sling in women with intrinsic sphincter deficiency: a multicentre prospective study. Int Urogynecol J. 2012 Feb;23(2):153-8.

Dean. (Updated 2010 Cochrane Rev) Laparoscopic colposuspension for urinary incontinence in women (Review). (2006)

Dean. [Review] Laparoscopic colposuspension and tension-free vaginal tape. A systematic review. BJOG 2006;113:1345–1353

Debodinance P. [Fr, Eng abs] Trans-obturator urethral sling for the surgical correction of female stress urinary incontinence: Ouside-in (Monarc) versus inside-out (TVT-O) are the two ways reassuring? European Journal of Obstetrics & Gynecology and Reproductive Biology 133 (2006) 232-238

Debodinance. [Pop 256, 3 mo fu] Tension-free vaginal tape (TVT) in the treatment of urinary stress incontinence: 3 years experience involving 256 operations. European Journal of Obstetrics & Gynecology and Reproductive Biology 105 (2002) 49-58

Deffieux X, Daher N, Mansoor A, Debodinance P, Muhlstein J, Fernandez H. Transobturator TVT-O versus retro pubic TVT: results of a multicenter randomized controlled trial at 24 months follow-up. Int Urogynecol J 2010;21:1337-1345.

Delorme (online Dec. 2003) - Transobturator tape (Uratape). A new minimally invasive procedure to treat female urinary incontinence. (2004)

Demirci F, et al. Long-term results of Burch colposuspension. Gynecol Obstet Invest 2001; 51:243-247.

Demirci, F., et al. "Long-Term Results of Burch Colposuspension", Gynecol Obstet Invest 2001; 51:243-247.

Denis. Pelvic Organ Prolapse Treatment by the Vaginal Route Using a Vypro Composite Mesh: Preliminary Results About 106 Cases. (2004)

DeSouza. [case report] Adductor brevis myositis following transobturator tape procedure: a case report and review of the literature. Int Urogynecol J (2007) 18:817–820

deTayrac R, et al. A prospective randomized trial comparing tension-free vaginal tape and transobturator suburethral tape for surgical treatment of stress urinary incontinence. American Journal of Obstetrics and Gynecology (2004) 190, 602e8

Case 2:12-md-02327 Document 2046-4 Filed 04/21/16 Page 9 of 37 PageID #: 39383 Bergmann, Cynthia - Materials List, updated 2.29.16.XLSX

Medical Literature

Di Piazza. IUGA Abs. 430 - Complications in short suburethral sling positioning. Int Urogynecol J (2009) 20 (Suppl 3):S241-S491.

Dietz H, et al. TVT vs Monarc: a comparative study. Int Urogynecol J (2006) 17: 566-569

Dietz HP. Mechanical properties of urogynecologic implant materials. Int Urogynecol J (2003) 14: 239–243.

Dmochowski RR, et al. (AUA Guidelines) Update of AUA Guideline on the Surgical Management of Female Stress Urinary Incontinence. *J Urol 2010 183: 1906-1914*.

Dooley Y, et al. Urinary Incontinence Prevalence: Results from the National Health and Nutrition Examination Survey. (2008)

Drahoradova P, Ma5ata J, Martan A, Svabfk K. ICS Abs. 278 - Comparative development of quality of life between TVT and Burch colposuspension. (2004)

Duckett J, Baranowski J. [Review] Pain after suburethral sling insertion for urinary stress incontinence. Int Urogynecol J (2013) 24:195-201

Duckett. [Pop 450, 3-50 mo fu] Groin pain after a tension-free vaginal tape or similar suburethral sling: management strategies. 2005 BJU INTERNATIONAL 95. 95-97

Dwyer. Carcinogenicity of implanted synthetic grafts and devices. (2014)

Dyrkorn. [Pop 5942] TVT compared with TVT-O and TOT: results from the Norwegian National Incontinence Registry. Int Urogynecol J (2010) 21:1321–1326

El-Barky E, El-Shazly A, El-Wahab OA, Kehinde EO, Al-Hunayan A, Al-Awadi KA. Tension free vaginal tape versus Burch colposuspension for treatment of female stress urinary incontinence. Int Urol Nephrol 2005;37:277-281.

Elena C, et al. [Pop 90] ISU Abs 5. - Can preoperative overactive bladder (OAB) symptoms influence TVT-O outcome? Neurourology and Urodynamics (2012)

El-Hefnawy AS, Wadie BS, El Mekresh M, Nabeeh A, Bazeed MA. TOT for treatment of stress urinary incontinence: how should we assess its equivalence with TVT? Int Urogynecol J 2010;21:947-953.

Elzevier H, et al. Female Sexual Function after Surgery for Stress Urinary Incontinence: Transobturator Suburethral Tape vs. Tension-Free Vaginal Tape Obturator. J Sex Med 2008;5:400-406

Elzevier. [Pop 96, 1 yr fu] Sexual function after tension-free vaginal tape (TVT) for stress incontinence: results of a mailed questionnaire. Int Urogynecol J (2004) 15: 313 318

Enhorning. Simultaneous recording of intravesical and intra-urethral pressure: A study on urethral closure in normal and stress incontinent women. (1961)

Eriksen. Long-term effectiveness of the Burch colposuspension in female urinary stress incontinence. Acta Obstet Gynecol Scand 1990; 69: 45 - 50

Falconer C, et al. Clinical Outcome and Changes in Connective Tissue Metabolism After Intravaginal Slingplasty in Stress Incontinent Women. Int Urogynecol J (1996) 7:133-137

Falconer C, Ulmsten U. Influence of Different Sling Materials on Connective Tissue Metabolism in Stress Urinary Incontinent Women. Int Urogynecol J (2001) (Suppl 2): S19-S23

Feyereisl. [Pop 87, 10 yr fu] Long-term results after Burch colposuspension. AM J OBSTET GYNECOL 1994;171:647-52.

Fitzgerald, Brubaker. Failure of allograft suburethral slings. BJU International (1999), 84, 785-788

Fong. [Review] Mid-urethral synthetic slings for female stress urinary incontinence. 2010 BJU INTERNATIONAL 106, 596–608

Case 2:12-md-02327 Document 2046-4 Filed 04/21/16 Page 10 of 37 PageID #: 39384 Bergmann, Cynthia - Materials List, updated 2.29.16.XLSX Medical Literature

Ford, AA et al. "Mid-urethral Sling Operations for Stress Urinary Incontinence in Women (Review)", Ford AA, Rogerson L, Cody JD, Ogah J. Mid-urethral sling operations for stress urinary incontinence in women. *Cochrane Database of Systematic Reviews* 2015, Issue 7. Art. No.: CD006375.

Francis. Dyspareunia following vaginal operations. The Journal of Obstetrics and Gynaecology (1961)

Freeman R, Holmes D, Hillard T, Smith P, James M, Sultan A, Morley R, Yang Q, Abrams P. What patients think: patient-reported outcomes of retropubic versus trans-obturator mid-urethral slings for urodynamic stress incontinence--a multi-centre randomised controlled trial. Int Urogynecol J. 2011 Mar;22(3):279-86.

Fuentes AE. A prospective randomised controlled trial comparing vaginal prolapse repair with and without tension free vaginal tape transobturator tape (TVT-O) in women with severe genital prolapse and occult stress incontinence: long term follow up. Int Urogynecol J 2011;22(Suppl I):S60-S61.

Fultz N, et al. Burden of Stress Urinary Incontinence for Community-Dwelling Women. (2003)

Galloway, Davies, Stephenson. The Complications of Colposuspension. British Journal of Urology (1987), 60, 142-124

Gamble, Goldberg, Sand. [Pop 41] ICS Abs 243 TVT versus bladder neck sling in the treatment of low pressure urethra. (2010)

Gandhi S, et al. TVT versus SPARC: comparison of outcomes for two midurethral tape prodecures. Int Urogynecol J (2006) 17: 125- 130

Ghezzi F, et al. Influence of the type of anesthesia and hydrodissection on the complication rate after tension-free vaginal tape procedure. European Journal of Obstetrics & Gynecology and Reproductive Biology 118 (2005) 96–100

Ghezzi F. et al. [Pop 53, 6 mo fu] Impact of tension-free vaginal tape on sexual function: results of a prospective study. Int Urogynecol J (2005) 17: 54–59

Ghezzi. [Pop 35, 36 mo fu] Tension-free vaginal tape for the treatment of urodynamic stress incontinence with intrinsic sphincteric deficiency. (2006)

Ghoniem G, Hammett J. Female pelvic medicine and reconstructive surgery practice patterns: IUGA member survey. Int Urogynecol J (2015)

Gilpin SA, et al. The pathogenesis of genitourinary prolapse and stress incontinence of urine. A histological and histochemical study. British Journal of Obstetrics and Gynaecology January 1989, Vol. 96, pp. 15-23

Glatt. The prevalence of dyspareunia. Obstet Gyencol 75: 433, 1990.

Glavind K and Shim Susy. Incidence and treatment of postoperative voiding dysfunction after the tensionfree vaginal tape procedure. Int Urogynecol J. June 2015.

Goode PS, Burgio KL, Locher JL, Roth DL, Umlauf MG, Richter HE, Varner RE, Lloyd LK: Effect of behavioral training with or without pelvic floor electrical stimulation on stress incontinence in women: a randomized controlled trial. JAMA 2003, 90(3):345-352

Greer WJ, et al. Obesity and pelvic floor disorders: a systematic review. Obstet Gynecol. 2008 Aug;112(2 Pt 1):341-9

Groutz A, et al. [Pop 52, 10 yr fu] Ten-year subjective outcome results of the retropubic tension-free vaginal tape for treatment of stress urinary incontinence. J Minim Invasive Gynecol (2011) 18:726-729

Groutz A, et al. [Pop 61, 5 yr fu] Long-term outcome of transobturator tension-free vaginal tape: efficacy and risk factors for surgical failure. J Women Health (2011) 20:1525–1528

Groutz A, et al. "Inside Out" Transobturator Tension-free Vaginal Tape for Management of Occult Stress Urinary Incontinence in Women Undergoing Pelvic Organ Prolapse Repair. 2010

Guerrero KL, Emery SJ, Wareham K, Ismail S, Watkins A, Lucas MG. [Pop 201, 1 yr fu] A randomised controlled trial comparing TVT, Pelvicol™ and autologous fascial slings for the treatment of stress urinary incontinence in women. BJOG 2010;117:1493-1502.

Hamer MA, et al. One-year results of a prospective randomized, evaluator-blinded, multicenter study comparing TVT and TVT Secur. Int Urogynecol J (2013) 24:223–229

Hamer MA, Larsson PG, Teleman P, Eten-Bergqvist C, Persson J. Short-term results of a prospective randomized evaluator blinded multicenter study comparing TVT and TVT-Secur. Int Uragynecol J Pelvic Floor Dysfunct 2011;22:781-787.

Han JY, et al. Effectiveness of retropubic tension-free vaginal tape and transobturator inside-out tape procedures in women with overactive bladder and stress urinary incontinence. Int Neurourol J. 2013 Sep;17(3):145-51

Han JY, et al. Efficacy of TVT-Secur and factors affecting cure of female stress urinary incontinence: 3-year follow-up. Int Urogynecol J (2012) 23:1721–1726

Handa, Ostergard. Banked Human Fascia Lata for the Suburethral Sling Procedure: A Preliminary Report. (1996)

Hannestad. A community-based epidemiological survey of female urinary incontinence: The Norwegian EPINCONT Study. Journal of Clinical Epidemiology 53 (2000) 1150-1157

Heinonen P. [Pop 191, mean 10.5 yrs fu] Tension-free vaginal tape procedure without preoperative urodynamic examination: Long-term outcome. Int J Urol 2012; 19:1003–1009

Hellberg D, et al. The very obese woman and the very old woman: tensionfree vaginal tape for the treatment of stress urinary incontinence. Int Urogynecol J (2007) 18:423–429

Hinoul P, et al. A Randomized, Controlled Trial Comparing an Innovative Single Incision Sling With an Established Transobturator Sling to Treat Female Stress Urinary Incontinence. J Urology (April 2011) Vol. 185, 1356-1362,

Hinoul P, Vervest HAM, Venema P, Den Boon J, Milani A, Roovers J. [119, 1 yr fu] IUGA Abs 166 - TVT obturator system versus TVT Secur: a randomized controlled trial, short term results. Int Uragynecol J Pelvic Floor Dysfunct 2009;20:S213.

Hinoul P. Anatomical variability in the trajectory of the inside-out transobturator vaginal tape technique (TVT-O). Int Urogynecol J (2007) 18:1201–1206

Hinoul P. Surgical Management of Urinary Stress Incontinence in Women: A Historical and Clinical Overview. European Journal of Obstetrics & Gynecology and Reproductive Biology 145 (2009) 219-225

Hinoul P. Surgical management of urinary stress incontinence in women: A historical and clinical overview. European Journal of Obstetrics & Gynecology and Reproductive Biology 145 (2009) 219-225

Hinoul, Waltregny, de Leval. [cadaver] (IUJ, not mtg abs) An anatomic comparison of the original versus a modified inside-out transobturator procedure. Int Urogynecol J (2011) 22:997–1004

Holmgren C, et al. [Pop 463, 5.2 yr fu] Frequency of de novo urgency in 463 women who had undergone the tension-free vaginal tape (TVT) procedure for genuine stress urinary incontinence - A long-term follow-up. European Journal of Obstetrics & Gynecology and Reproductive Biology 132 (2007) 121-125

Holmgren CG, et al. Long-Term Results with Tension-Free Vaginal Tape on Mixed and Stress Urinary Incontinence. Obstetrics & Gynecology, Vol. 106, No. 1, July 2005, 38-43

Holmgren. Quality of life after tension-free vaginal tape surgery for female stress incontinence. (2006)

Horbach, Ostergard, Bent. A Suburethral Sling Procedure with Polytetrafluoroethylene for the treatment of Genuine stress incontinence in patients with low urethral closure pressure. (1988)

Hota LS, Hanaway KJ, Hacker MR, et al. TVT-secur (Hammock) versus TVT-obturator: a randomized trial of suburethral sling operative procedures. Female Pelvic Med Reconstr Surg 2010;16:S87.

Houwert RM, et al. TVT-O versus Monarc after a 2-4 year follow-up: a prospective comparative study. Int Urogynecol J (2009) 20: 1327-1333

Hu. Costs of urinary incontinence and overactive bladder in the United States: A comparative study. UROLOGY 63: 461–465, 2004

Huang. High failure rate using allograft fascia lata in pubovaginal sling surgery for female stress urinary incontinence. UROLOGY 58: 943-946, 2001

Hwang E., et al. Predictive factors that influence treatment outcomes of innovative single incision sling: comparing TVT-Secur to an established transobturator sling for female stress urinary incontinence. Int Urogynecol J (2012) 23:907–912

Imamura. Systematic review and economic modelling of the effectiveness and cost-effectiveness of nonsurgical treatments for women with stress urinary incontinence. (2010)

Jamieson, Steege - The Prevalence of Dysmenorrhea, Dyspareunia, Pelvic Pain, and Irratable Bowel Syndrome in Primary Care Practices. Obstet Gynecol 1996; 87: 55-8.

Jarvis. Ltr re Weiss Erosion of buttress following bladder neck suspension. British Journal of Urology (1992), 70,695-698

Jarvis. Surgery for genuine stress incontinence. British Journal of Obstetrics and Gynaecology, May 1994, Vol. 101, pp. 371-374

Jelovsek JE, Barber MD, Karram MM, Walters MD, Paraiso MFR. Randomised trial of laparoscopic Burch colposuspension versus tension-free vaginal tape: long-term follow up. BJOG 2008;115:219-225; discussion 225.

Jha. [Meta-analysis] Impact of incontinence surgery on sexual function. A systematic review and meta-analysis. J Sex Med 2012;9:34–43

Jha. Surgical Management of Stress Urinary Incontinence: A Questionnaire Based Survey. [IUGA] European Urology 47 (2005) 648–652

Jha. The impact of TVT on sexual function. Int Urogynecol J (2009) 20:165-169

Jonsson-Funk M, et al. (published) Sling revision/removal for mesh erosion and urinary retention: long-term risk and predictors. Am J Obstet Gynecol. 2013 January; 208(1): 73.e1-73.e7.

Jonsson-Funk M. Trends in the Surgical Management of Stress Urinary Incontinence [United States]. Obstet Gynecol. 2012 April; 119 (4):845-851.

Juang C-M, Yu K-J, Chou P, et al. Efficacy analysis of trans-obturator tension-free vaginal tape (TVT-0) plus modified Ingelman-Sundberg procedure versus TVT-O alone in the treatment of mixed urinary incontinence: a randomized study. Eur Ural 2007;51:1671-1678;

Kaelin-Gambirasio I, et al. Complications associated with transobturator sling procedures: analysis of 233 consecutive cases with a 27 months follow-up. BMC Women's Health 2009, 9:28

Kaplan. Comparison of fascial and vaginal wall slings in the management of intrinsic sphincter deficiency. (1996)

Karateke A, et al. Comparison of TVT and TVT-O in patients with stress urinary incontinence: short-term cure rates and factors influencing the outcome. A prospective randomised study. Aust N Z J Obstet Gynaecol. 2009 Feb;49(1):99-105.

Karram M, Brown ET. Avoiding and Managing Complications of Synthetic Midurethral Slings. Curr Bladder Dysfunct Rep (2015) 10:64-70.

Karram M, et al. Complications and Untoward Effects of the Tension-Free Vaginal Tape Procedure. The American College of Obstetricians and Gynecologists (2003) Vol. 101, No. 5, Part 1

Karram M. [OB Mgmt] When and how to place an autologous rectus fascia pubovaginal sling. OBG Management, 24:11, Nov. 2012

Kavvadias, Klinge. (TVT is gold) Ch 56 Alloplastic Implants for the Treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse. ISBN 978-3-642-04552-3 Springer-Verlag Berlin Heidelberg New York

Keegan. Periurethral injection therapy for urinary incontinence in women (Review) (2007)

Kenton K, Zyczynski H, Sirls LT, Richter HE, et al. (TOMUS published) 5-Year Longitudinal Followup after Retropubic and Transobturator Mid-urethral slings. The Journal of Urology, Vol. 193, 203-210, January 2015.

Khan Z, et al. [Pop 162, 10 yr fu] Long-term follow-up of a multicentre randomised controlled trial comparing tension-free vaginal tape, xenograft and autologous fascial slings for the treatment of stress urinary incontinence in women BJU Int 2015: 115: 968-977

Khandwala S, et al. Experience with TVT-Secur sling for stress urinary incontinence: a 141-case analysis. Int Urogynecol J (2010) 21:767–772

Kim. [Pop 115, 12 mo fu] Randomized Comparative Study of the U-and H-type Approaches of the TVT-Secur Procedure for the Treatment of Female Stress Urinary Incontinence: One Year Follow-Up. Korean J Urol 2010;51:250-256

King A. Is there an association between polypropylene midurethral slings and malignancy. Urology 84: 789-792, 2014

Kinn. [Pop 153, 5 yr fu] Burch colposuspension for stress urinary incontinence. 5-year results in 153 women. Scand JUral Nephrol 29: 449-455, 1995

Kjolhede - [Pop 21] Prediction of genital prolapse after Burch colposuspension. Acta Obstet Gynecol Scand 1996; 75: 849-854

Kjolhede - [Pop 232, median 6 yr fu] Prognostic factors and long-term results of the Burch colposuspension. Acta Obstet Gynecol Scand 1994; 73: 642-647.

Kjolhede P. BURCH - Long-term Efficacy of Burch Colposuspension: A 14-year Follow-up Study. Acta Obstet Gynecol Scand 2005; 84: 767–772.

Klinge - Do multifilament alloplastic meshes increase the infection rate? Analysis of the Polymeric Surface, the Bacteria Adherence, and the In Vivo Consequences in a Rat Model. J Biomed Mater Res (Appl Biomater) 63: 765–771, 2002

Klinge U, et al. Demands and Properties of the Alloplastic Implants for the Treatment of Stress Urinary Incontinence. Expert Rev. Med. Devices 4(3), 349–359 (2007)

Kobashi K, et al. Erosion of woven Polyester Pubovaginal Sling. J Urology, Vol. 162, 2070–2072, December 1999

Kolle D, et al. Bleeding Complications With The Tension-Free Vaginal Tape Operation. American Journal of Obstetrics and Gynecology (2005) 193. 2045-9

Kondo A, I so be Y, Kimura K, et al. [Pop 60, 24 mo fu] Efficacy, safety and hospital costs of tension-free vaginal tape and pubovaginal sling in the surgical treatment of stress incontinence. J Obstet Gynaecol Res 2006;32:539-544.

Kondo. [Pop 57, 2 yr fu] A randomised control trial of tension-free vaginal tape in comparison with pubovaginal sling in the treatment of stress incontinence. (2003)

Krofta L, et al. TVT and TVT-O for surgical treatment of primary stress urinary incontinence: prospective randomized trial. Int Urogynecol J (2010) 21:141–148

Krofta L, et al. TVT-S for surgical treatment of stress urinary incontinence: prospective trial, 1-year follow-up. Int Urogynecol J (2010) 21:779–785

Kulseng-Hanssen S. Follow-up of TVT Operations in 1,113 women with mixed urinary incontinence at 7 and 38 months. Int Urogynecol J (2008) 19:391–396

Kuuva, Nilsson. [Pop 129, 6 yr fu] Long-term results of the tension-free vaginal tape operation in an unselected group of 129 stress incontinent women. Acta Obstetricia et Gynecologica. 2006; 85: 482 -487

Kuuva, Nilsson. [Pop 1455, 2 mo fu] A nationwide analysis of complications associated with the tension-free vaginal tape (TVT) procedure. Acta Obstet Gynecol Scand 2002; 81: 72–77

Labrie J, et al. Protocol for Physiotherapy Or TVT Randomised Efficacy Trial (PORTRET): a multicentre randomized controlled trial to assess the cost-effectiveness of the tension free vaginal tape versus pelvic floor muscle training in women with symptomatic moderate to severe stress urinary incontinence. BMC Womens Health. 2009;9:24

Labrie J. Surgery versus Physiotherapy for Stress Urinary Incontinence. N Engl J Med (2013) 369:12, 1124-33.

Lamers, BHC, van der Vaart, CH. Medium-term efficacy of pelvic floor muscle training for female urinary incontinence in daily practice. Int Urogynecol J Pelvic Floor Dysfunct 2007, 18(3):301-307

Lane. Repair of posthysterectomy vaginal-vault prolapse. The Journal of Obstetrics and Gynaecology (1962) Vol. 20, No. 1. pp. 72-77.

Lapitan M. (Cochrane Rev) Open retropubic colposuspension for urinary incontinence in women (Review). The Cochrane Collaboration (2012)

Latthe PM, Foon R, Toozs-Hobson P. Transobturator and retropubic tape procedures in stress urinary incontinence: a systematic review and meta-analysis of effectiveness and complications. BJOG (2007) 114:522–531

Latthe PM, Singh P, Foon R, Toozs-Hobson P. [Meta-analysis] Two routes of transobturator tape procedures in stress urinary incontinence: a meta-analysis with direct and indirect comparison of randomized trials. BJUI (2009) 106, 68-76

Laumann. Sexual Dysfunction in the United States: Prevalence and Predictors. JAMA. 1999;281:537-544

Laurikainen E, et al. [Pop 267, 2 mo fu] Retropubic Compared With Transobturator Tape Placement in Treatment of Urinary Incontinence: a randomized controlled trial. J Obstet Gynecol 2007;109:4-11

Laurikainen E, Takala T, Aukee P, et al. Retropubic TVT compared with transobturator TVT (TVT-O) in treatment of stress urinary incontinence: five-year results of a randomized trial. Neuraural Uradyn 2011;30:803-805.

Laurikainen E, Valpas A, Aukee P, Kivelä A, Rinne K, Takala T, Nilsson CG. [Pop 254, 5 yr fu] Five-year results of a randomized trial comparing retropubic and transobturator midurethral slings for stress incontinence. Eur Urol (2014) 65:1109-1114

Laurikainen E. Five-year results of a randomized trial comparing retropubic and transobturator midurethral slings for stress incontincence. 2014; Eur Urol. Jan 31. pii: S0302-2838(14)00100-6.

Lebret. (French, Eng abs at end) [Pop 100, mean 5 yr fu] Long-term results of isolated Burch colposuspension of the bladder neck in the treatment of female urinary stress incontinence. Progres en Urologie (1997), 7, 426-432.

Lee EW, et al. Midurethral Slings for All Stress Incontinence A Urology Perspectiv. Urol Clin N Am 39 (2012) 299-310.

Lee Kry-Sung, et al. A prospective multicenter randomized comparative study between the U- and H- type methods of the TVT Secur procedure for the treatment of female stress urinary incontinence: 1- year follow-up. European Urology (2010) 973-979.

Lee Kyu-Sung, et al. A prospective trial comparing tension-free vaginal tape and transobturator vaginal tape inside-out for the surgical treatment of female stress urinary incontinence: 1-year followup. J Ural 2007;177:214-218.

Lee Kyu-Sung, et al. Prospective comparison of the 'inside-out' and 'outside-in' transobturator-tape procedures for the treatment of female stress urinary incontinence. Int Uragynecol J Pelvic Floor Dysfunct 2008:19:577-582.

Lee, Zimmern. Long-Term Outcomes of Autologous Pubovaginal Fascia Slings: Is there a difference between primary and secondary slings? (2013)

Lemack, Nager, Sirls, Zyczynski, (UITN). Normal Preoperative Urodynamic Testing Does Not Predict Voiding Dysfunction After Burch Colposuspension Versus Pubovaginal Sling. (2008)

Li B, Zhu L, Lang JH, Fan R, et al. [Pop 55, 7 yr fu] Long-term outcomes of the tension-free vaginal tape procedure for female stress urinary incontinence: 7-year follow-up in China. J Minim Invasive Gynecol. 2012 Mar-Apr;19(2):201-5.

Liapis [Pop 65, 5 & 7 yr fu] Long-term efficacy of tension-free vaginal tape in the management of stress urinary incontinence in women: efficacy at 5- and 7-year follow-up. Int Urogynecol J (2008) 19:1509-1512

Liapis A, Bakas P, Christopoulos P, Giner M, Creatsas G. Tension-free vaginal tape for elderly women with stress urinary incontinence. Int J Gynaecol Obstet 2006;92:48-51.

Liapis A, Bakas P, Creatsas G. [Pop 115, 4 yr fu] Efficacy of inside-out transobturator vaginal tape (TVTO) at 4 years follow-up. Eur J Obstet Gynecol Reprod Biol (2010) 148:199-201

Liapis A, Bakas P, Creatsas G. [Pop 71] Burch colposuspension and tension-free vaginal tape in the management of stress urinary incontinence in women. Eur Urol. 2002 Apr;41(4):469-473.

Liapis A, Bakas P, Creatsas G. Monarc vs TVT-O for the treatment of primary stress incontinence: a randomized study. Int Uragynecol J Pelvic Floor Dysfunct 2008;19:185-190.

Liapis A. [Pop 65, 5 & 7 yr fu] Long-term efficacy of tension-free vaginal tape in the management of stress urinary incontinence in women: efficacy at 5- and 7-year follow up. Int Urogynecol J 2008; 19:1509–1512.

Liapis A. Efficacy of inside-out transobturator vaginal tape (TVTO) at 4 years follow up. European Journal of Obstetrics & Gynecology and Reproductive Biology 148 (2010) 199-201

Liapis A. Tension-Free Vaginal Tape versus Tension-Free Vaginal Tape Obturator in Women with Stress Urinary Incontinence. Gynecol Obstet Invest 2006;62:160-164

Lim J, et al. Short-term clinical and quality-of-life outcomes in women treated by the TVT-Secur procedure. Australian and New Zealand Journal of Obstetrics and Gynaecology 2010; 50: 168–172

Lim JL. Clinical and quality-of-life outcomes in women treated by the TVT-O procedure. BJOG 2006;113:1315–1320.

Lim YN, Muller R, Corstiaans A, Dietz HP, Barry C, Rane A. Suburethral slingplasty evaluation study in North Queensland, Australia: the SUSPEND trial. Australian NZ J Obstet Gynaecol 2005;45:52-59.

Lim. [Pop 664] Do the Advantage slings work as well as the tension-free vaginal tapes? Int Urogynecol J (2010) 21:1157–1162

Lin AT, et al. In vivo tension sustained by fascial sling in pubovaginal sling surgery for female stress urinary incontinence. J Urol. 2005 Mar;173(3):894-7.

Linder BJ, Evaluation of the local carcinogenic potential of mesh used in the treatment of female stress urinary incontinence. Int Urogynecol J 2016 DOI 10.1007/s00192-016-2961=4

Lleberia J, et al. Surgical Treatment of Mixed Urinary Incontinence: effect of anterior colpoplasty. Int Urogynecol J (2011) 22:1025-1030

Lo. [Pop 70, 3 yr fu] Ultrasound assessment of mid-urethra tape at three-year follow-up after tension-free vaginal tape procedure. UROLOGY 63:671–675, 2004

Lord HE, Taylor JD, Finn JC, et al. A randomized controlled equivalence trial of short-term complications and efficacy of tension-free vaginal tape and supra pubic urethral support sling for treating stress incontinence. BJU Int 2006;98:367-376.

Lose. [Pop 80, mean 26 mo fu] Voiding difficulties after colposuspension. Obstet Gynecol 69:33, 1987

Luber. The definition, prevalence, and risk factors for stress urinary incontinence. (2004)

Lucas, MG. EAU Guidelines on Surgical Treatment of Urinary Incontinence. Eur Urol. 2012; 62:1118-29

Lucente VR, Cassidenti AP, Culligan PJ. The FDA and Mesh, what you should know as a Reconstructive Pelvic Surgeon. Final 02.9.2016

Lukacz, Nager. [Pop 54, 1 yr fu] The effects of the tension-free vaginal tape on proximal urethral position: a prospective, longitudinal evaluation. Int Urogynecol J (2003) 14: 179–184

Maaita M. [Pop 57, 36 mo fu] Sexual function after using tension-free vaginal tape for the surgical treatment of genuine stress incontinence. BJU International (2002), 90, 540–543

Magno-Azevedo V. Single Incision Slings: Is There a Role? Curr Bladder Dysfunct Rep (2013) 8:19-24

Maher C, Qatawneh A, Baessler K, Croppe M, Schluter P. [Pop 82] Abs. 25 Laparoscopic colposuspension or tension-free vaginal tape for recurrent stress urinary incontinence and/or intrinsic sphincter deficiency-a randomised controlled trial. Neurourol Urodyn 2004;23:433-434.

Maldonado PA, et al. Patient satisfaction following midurethral sling surgeries. Curr Opin Obstet Gynecol 2014, 26:404-408.

Markland AD, et al. Prevalence and trends of urinary incontinence in adults in the United States, 2001 to 2008. (2011)

Martan A. TVT SECUR System - Tension-free Support of the Urethra in Women Suffering from Stress Urinary Incontinence - Technique and Initial Experience. Ces. Gynek. 72, 2007, C. 1 s.42-49

Masata J, et al. Randomized trial of a comparison of the efficacy of TVT-O and single-incision tape TVT Secur systems in the treatment of stress urinary incontinent women –2-year follow-up. Int Urogynecol J (2012) 23:1403–1412

Masata J, Svabik K, Drahoradova P, et al. Randomized prospective trial of a comparison of the efficacy of TVT-0 and TVT secur system in the treatment of stress urinary incontinent women - comparison of the long-and short-term results. Neurourol Urodyn 2011;30:805-806.

Mathias, Steege. Chronic Pelvic Pain. Prevalence, Health-Related Quality of Life, and Economic Correlates. Obstet Gynecol 1996;87:321-7

Case 2:12-md-02327 Document 2046-4 Filed 04/21/16 Page 17 of 37 PageID #: 39391 Bergmann, Cynthia - Materials List, updated 2.29.16.XLSX Medical Literature

McGregor. Evaulation of the carcinogenic Risks to humans associated with surgical implants and other foreign bodies - a report of an IARC Monographs Programme Meeting. European Journal of Cancer 36 (2000) 307-313

McLennan M, et al. Bladder Perforation During Tension-Free Vaginal Tape Procedures: Abdominal versus Vaginal Approach. Female Pelvic Medicine & Reconstructive Surgery, Volume 18, Number 1, January/February 2012

Meschia M, et al. [Pop 95, 12 mo fu] Multicenter prospective trial of TVT Secur for the treatment of primary stress urinary incontinence. Urogynaecolgia International Journal Vol. 22n.2 - May-Aug. 2008

Meschia M, et al. Tension-free vaginal tape: analysis of risk factors for failures. Int Urogynecol J (2007) 18:419–422

Meschia M, Pifarotti P, Bernasconi F, et al. Tension-free vaginal tape (TVT) and intravaginal slingplasty (IVS) for stress urinary incontinence: a multi center randomized trial. Am J Obstet Gynecol 2006;195:1338-1342.

Meschia M, Pifarotti P, Spennacchio M, Buonaguidi A, Gattei U, Somigliana E. [Pop 50, 24-26 mo fu] A randomized comparison of tension-free vaginal tape and endopelvic fascia plication in women with genital prolapse and occult stress urinary incontinence. Am J Obstet Gynecol 2004;190:609-613.

Mirosh. [Pop 30, 1 yr fu] ICS Abs 640 TVT vs. Laparoscopic Burch Colposuspension for the Treatment of Stress Urinary Incontinence. (2006)

Moalli P, et al. Tensile properties of file commonly use mid-urethral slings relative to the TVT. Int Urogynecol J (2008) 19:655 663

Moalli, Nager. Polypropylene mesh: evidence for lack of carcinogenicity. Int Urogynecol J (2014)

Moen, Matthews - SGS Oral Poster 5 A comparison of midurethral sling versus burch urethropexy for treating urodynamic stress incontinence at the time of abdominal sacrocolpopexy. Journal of Pelvic Medicine & Surgery • Volume 15, Number 2, March/April 2009

Moore, Miklos - ICS Abs 827 - MiniArc single incision sling: 1 year follow-up on a new minimally invasive treatment for female SUI. (2009)

Moore, Miklos - IUGA Abs 298 - Single incision mini-sling. 1 year follow-up on a new minimally invasive treatment for female SUI. Int Urogynecol J (2009) 20 (Suppl 3): S241-S429

Morgan. A sling operation, using Marlex polypropylene mesh, for treatment of recurrent SUI. Amer. J. Obstet, Gynec. February 13, 1970.

Morgan. The Marlex sling operation for the treatment of recurrent stress urinary incontinence: A 16-year review (1985)

Mundy. A Trial Comparing the Stamey Bladder Neck Suspension Procedure with Colposuspension for the Treatment of Stress Incontinence. British Journal of Urology (1983). 55, 687-690

Muzsnai. Retropubic vaginopexy for correction of urinary stress incontinence. Obstetrics & Gynecology, Vol. 59, No. 1 January 1982.

Nager CW. AUGS - Final Presidential Blog (2014)

Nager CW. Synthetic full-length midurethral slings remain the standard of care for SUI surgery. OBJ Management, November 2012, Vol. 24, No. 11

Nager, Lemack. Design of the Value of Urodynamic Evaluation (ValUE) Trial: A Non-Inferiority Randomized Trial of Preoperative Urodynamic Investigations. Contemp Clin Trials. 2009 November; 30(6): 531–539

Nager, Sirls, Kenton, Richter (UITN) - (VALUE) A Randomized Trial of Urodynamic Testing before Stress-Incontinence Surgery. N Engl J Med 366; 21, May 2012

Nerli RB, Kumar AG, Koura A, Prabha V, Alur SB. [Pop 36] (TOT) Transobturator vaginal tape in comparison to tensionfree vaginal tape: A prospective trial with a minimum 12 months follow-up. Indian J Urol 2009;25:321-325.

Neuman M. [Pop 100, 1 yr fu] Perioperative Complication and Early Follow-up with 100 TVT-Secur Procedures. Journal of Minimally Invasive Gynecology (2008) 15,480-484

Neuman M. [Pop 100] TVT-SECUR. 100 teaching operations with a novel anti-incontinence procedure. Pelviperineology 2007; 26:121-123.

Neuman M. [Pop 162, 3 yr fu] Transobturator vs. Single-Incision Suburethral Mini-slings for Treatment of Female Stress Urinary Incontinence: Early Postoperative Pain and 3-Year Follow-up. Journal of Minimally Invasive Gynecology (2011) 18, 769–773

Neuman M. [Pop 620 -8 yr fu TVT, 350-2yr fu TVT-O] IUGA Abs 081 - TVT and TVT-Obturator: Comparison of Two Operative Procedures. Int Urogynecol J (2006) 17 (Supp. 2) S101-152

Neuman M. Post Tension-free Vaginal Tape Voiding Difficulties. Journal of Pelvic Medicine and Surgery, Volume 10, Number 1, January/February 2004

Nguyen J. [Pop 4,142] Perioperative Complications and Reoperations After Incontinence and Prolapse Surgeries Using Prosthetic Implants, Obstet Gynecol. 2012 Mar;119(3):539-46

NICE "Urinary Incontinence: The Management of Urinary Incontinence in Women", ICE clinical guideline 171 guidance.nice.org.uk/cg171 (September 2013).

Nichols. The Mersilene Mesh Gauze-Hammock for Severe Urinary Stress Incontinence. The Journal of Obstetrics and Gynaecology (1973) Vol. 41, No. 1. pp. 88-93.

Niemczyk. [Pop 100, 2 mo fu] United States Experience with Tension-Free Vaginal Tape Procedure for Urinary Stress Incontinence: Assessment of Safety and Tolerability. Techniques in Urology Vol. 7, No. 4, pp. 261 - 265

Nilsson C. [Pop 80, 7 yr fu] Seven-Year Follow-up of the Tension-Free Vaginal Tape Procedure for Treatment of Urinary Incontinence. Obstet Gynecol (2004) 104, 1259-1262.

Nilsson C. Creating a gold standard surgical procedure. The development and implementation of TVT (Ulf Ulmsten Memorial Lecture 2014). Int Urogynecol J DOI 10.1007/s00192-014-2616-2

Nilsson CG, et al. Long-term Results of the Tension-Free Vaginal Tape (TVT) Procedure for Surgical Treatment of Stress Urinary Incontinence. Int Urogynecol J (2001) (Suppl 2):S5-S8.

Nilsson CG. [Pop 90, median 56 mo fu] Long-term Results of the Tension-free Vaginal Tape (TVT) Procedure for Surgical Treatment of Female Stress Urinary Incontinence. Int Urogynecol J 2001 (Suppl 2): S5-S8

Nilsson CG. [Pop 58, 17 yrs fu] Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence. Int Urogynecol J. 2013;24(8):1265-9

Nilsson CG. Eleven years prospective follow-up of the tension free vaginal tape procedure for treatment of stress urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct 2008; 19:1043–1047.

Nilsson M, et al. (Swedish Registry) [Pop 3334, 12 mo fu] Female urinary incontinence: patient-reported outcomes 1 year after midurethral sling operations. Int Urogynecol J. 2012 Oct;23(10):1353-9.

Nilsson. Creating a gold standard surgical procedure. The development and implementation of TVT (Ulf Umsten Memorial Lecture 2014) 2015.

North, C., et al. A 2-year observational study to determine the efficacy of a novel single incision sling procedure (Minitape) for female stress urinary incontinence. BJOG 2010; 117:356-360.

Norton, P. Collagen synthesis in women with Genital Prolapse or Stress Urinary Incontinence. (Abstract only

Novara G, et al. "Updated Systematic Review and Meta-Analysis of the Comparative Data on Colpsuspensions, Pubovaginal Slings, and Midurethral Tapes in the Surgical Treatment of Female Stress Urinary Incontinence", EUROPEAN UROLOGY 58 (2010) 218–238.

Medical Literature

Novara G, Galfano A, Boscolo-Berto R, Secco S, Cavalleri S, Ficarra V, Artibani W. [meta-analysis] Complication rates of tension-free midurethral slings in the treatment of female stress urinary incontinence: a systematic review and meta-analysis of randomized controlled trials comparing tension-free midurethral tapes to other surgical procedures and different devices. Eur Urol. 2008 Feb;53(2):288-308.

Novara. [review\_meta-analysis] Tension-free midurethral slings in the treatment of female stress urinary incontinence: a systematic review and meta-analysis of randomized controlled trials fo effectiveness. european uro I ogy 52 ( 2007) 663 679

Nygaard I, et al. (Nager, PFDN) Prevalence of Symptomatic Pelvic Floor Disorders in US Women. JAMA 2008; 300(11):1311-1316.

Nygaard I. Long-Term Outcomes Following Abdominal Sacrocolpopexy for Pelvic Organ Prolapse, JAMA. 2013 May 15;309(19):2016-24

Ogah J, et al. Minimally Invasive Synthetic Suburethral Sling Operations for Stress Urinary Incontinence in Women: A Short Version Cochrane Review. *Neurourology and Urodynamics* 30:284–291 (2011).

Ogah J. (Short Cochrane Rev) Minimally invasive synthetic suburethral sling operations for Stress urinary Incontinence in Women: A Short Version Chochrane Review. Neurourology and Urodynamics 30:284-291 (2011)

Ogah J. Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women (Review). 2009 The Cochrane Collaboration

Oliphant. Trends in Stress Urinary Incontinence Inpatient Procedures in the US, 1979-2004. Am J Obstet Gynecol 2009;200:521.e1-521.e6

Oliveira LM et al. [Pop 85, med 14 mos fu] Abs 328 - Comparison of retro-pubic TVT, pre-pubic TVT and TVT transobturator in surgical treatment of women with stress urinary incontinence. Int Urogynecol J 2006; 17 (Suppl 2): 5171-5359

Oliveira R. [Pop 107, 15 mo fu] Short-term assessment of a tension-free vaginal tape for treating female stress urinary incontinence. BJU International (2008) 104, 225–228

Oliveira R. [Pop 90, 12 mo fu] Exploratory Study Assessing Efficacy and Complications of TVT-O, TVT-Secur, and Mini-Arc: Results at 12-Month Follow-Up. European Urology 3761 (2011)

Olsen A. Epidemiology of Surgically Managed Pelvic Organ Prolapse and Urinary Incontinence. Obstet Gynecol 1997;89:501-6.

Olsson I, Abrahamsson AK, Kroon UB. [Pop 147, 11.5 yrs fu] Long-term efficacy of the tension-free vaginal tape procedure for the treatment of urinary incontinence: a retrospective follow-up 11.5 years post-operatively. Int Urogynecol J (2010) 21:679-683

Osborn DJ. Obesity and female stress urinary incontinence. Urology. 2013 Oct;82(4):759-63

Ozel. The impact of pelvic organ prolapse on sexual function in women with urinary incontinence. Int Urogynecol J (2005) 17: 14–17

Padilla-Fernández B, et al. Results of the surgical correction of urinary stress incontinence according to the type of transobturator tape utilized. Arch Ital Urol Androl. 2013;85:149-53.

Case 2:12-md-02327 Document 2046-4 Filed 04/21/16 Page 20 of 37 PageID #: 39394 Bergmann, Cynthia - Materials List, updated 2.29.16.XLSX Medical Literature

Palomba S, Oppedisano R, Torella M, Falbo A, Maiorana A, Materazzo C, Tartaglia E, Tolino A, Mastrantonio P, Alio L, Colacurci N, Zullo F; SIMS Italian Group. [Pop 120, 64 mo fu] A randomized controlled trial comparing three vaginal kits of single-incision mini-slings for stress urinary incontinence: surgical data. Eur J Obstet Gynecol Reprod Biol. 2012 Jul;163(1):108-12.

Palva, Nilsson. [Pop 267, 36 mo fu] A randomized trial comparing tension-free vaginal tape with tension-free vaginal tape-obturator: 36-month results. Int Urogynecol J (2010) 21:1049 1055

Paraiso MF, Walters MD, Karram MM, et al. [Pop 72, 2 yr fu] Laparoscopic Burch colposuspension versus tension-free vaginal tape: a randomized trial. Obstet Gynecol. 2004 Dec;104(6):1249-58. PubMed PMID: 15572485.

Paraiso. [Pop 72, 2 yr fu] Laparoscopic Burch Colposuspension versus Tension-free Vaginal Tape: A Randomized Trial. Obstet Gynecol 2004;104:1249-58

Parden AM, Richter HE, et al. [Pop 1316, median 36.4 mo fu] Incontinence outcomes in women undergoing primary and repeat midurethral sling procedures. Obstet Gynecol. 2013 February; 121(201):273-278.

Parnell. Management of recurrent urinary stress incontinence by the Marshall-Marchetti-Krantz vesicourethropexy. The Journal of Urology, Vol. 132, pp 912-914, (1984)

Patel. [Pop 150, median 8 mos] Is Burch or mid-urethral sling better with abdominal sacral colpopexy? Int Urogynecol J (2009) 20:787–790

Pauls, Karram. Practice Patterns of physician members of the [AUGS] regarding female sexual dysfunction: results of a national survey. Int Urogynecol J (2005) 16: 460–467

Perkins CE, et al. The Role of Mid-urethral Slings in 2014: Analysis of the Impact of Litigation on Practice. Curr Bladder Dysfunct Rep (2015) 10:39-45.

Petros P, Ulmsten U. An integral theory and its method for the diagnosis and management of female urinary incontinence. Scand J Urol Nephral Suppl. No. 153, 1993.

Petros P. Creating a gold standard device. Scientific discoveries leading to TVT and beyond (Ulf Ulmsten Memorial Lecture 2014). Int Urogynecol J 2015. DOI 10.1007/s00192-015-2639-3

Petros, Ulmsten. An integral theory of female urinary incontinence: Experimental and clinical considerations. Acta Obstet Gynecol Scand 1990; 69 Suppl 153: 7-31.

Petrou, Blaivas. Suprameatal Transvaginal Urethrolysis. (1999)

Phillips. [case report] Case report of tension-free vaginal tape-associated bowel obstruction and relationship to body habitus. Int Urogynecol J (2009) 20:367–368

Pifarotti. [Pop 18, 1 yr fu] A randomized prospective comparison of TVT and endopelvic fascia plication in the treatment of occult stress urinary incontinence in patients with genital prolapse: preliminary data. Urogynaecologia International Journal Vol. 15, N. 1 Jan-Apr. 2001.

Polichetti. IUGA Abs. 557 SUS (suburethral support): a new technique for short suburethral sling application. Int Urogynecol J (2009) 20 (Suppl 3): S241-S429

Porena M, Costantini E, Frea B, et al. [Pop 148, mean 31 mo fu] Tension-free vaginal tape versus transobturator tape as surgery for stress urinary incontinence: results of a multicentre randomised trial. Eur Urol 2007;52:1481-1490.

Pradhan A, et al. [meta-analysis] Effectiveness of midurethral slings in recurrent stress urinary incontinence: A systematic review and meta-analysis. Int Urogynecol J (2012) 23:831-841.

Prien-Larsen. [Pop 316, 5 yr fu] Long-term outcomes of TVT and IVS operations for treatment of female stress urinary incontinence: monofilament vs. multifilament polypropylene. Int Urogynecol J (2009) 20:703–709

Case 2:12-md-02327 Document 2046-4 Filed 04/21/16 Page 21 of 37 PageID #: 39395 Bergmann, Cynthia - Materials List, updated 2.29.16.XLSX Medical Literature

Pulliam S. Use of synthetic mesh in pelvic reconstructive surgery: a survey of attitudes and practice patterns of urogynecologists. Int Urogynecol J (2007) 18:1405 1408

Rechberger T, Rzezniczuk K, Skorupski P, et al. A randomized comparison between monofilament and multifilament tapes for stress incontinence surgery. Int Urogynecol J Pelvic Floor Dysfunct 2003;14:432-436.

Rechberger T. FASCIAL SLINGS - Role of fascial collagen in stress urinary incontienence. Am J Obstet Gynecol (1998) 1511-1514

Rechberger. (Polish\_Eng abstract) The tissue reaction to polypropylene mono-et multifilamentous tape used in surgical techniques of stress urinary incontinence treatment. GIN. POL., 2003, 74,9

Rehman. [Cochrane Review] Traditional suburethral sling operations for urinary incontinence in women (Review). 2011 The Cochrane Collaboration

Reich. [7 yr fu] Long-term results of the tension-free vaginal tape procedure in an unselected group: a 7-year follow-up study. ROLOGY 78:774-777, 2011

Renganathan. A series of Advantage suburethral slings. 2011 The Cochrane Collaboration Journal of Obstetrics and Gynaecology, August 2011; 31: 521–523

Rezapour M, et al. [Pop 49, Mean 4 yr fu] Tension-Free Vaginal Tape (TVT) in Stress Incontinent Women with Intrinsic Sphincter Deficiency (ISD) - A Long-Term Follow-up. Int Urogynecol J (2001) (Suppl 2):S12-S14.

Rezapour M, Ulmsten U. [Pop 34, 4 yr fu] Tension-Free Vaginal Tape (TVT) in Women with Recurrent Stress Urinary Incontinence – A Long-term Follow Up. Int Urogynecol J (2001) (Suppl 2):S9-S11.

Rezapour M, Ulmsten U. [Pop 80, 4 yr fu] Tension-Free Vaginal Tape (TVT) in Women with Mixed Urinary Incontinence - A Long-Term Follow-up. Int Urogynecol J (2001) (Suppl 2):S15-S18.

Richter HE, et al. A trial of continence pessary compared with behavioral therapy vs. combined therapy for stress incontinence-a randomized controlled trial. Obstet Gynecol. 2010 March; 115(3): 609-617.

Richter HE, Kenton KS. (UITN) (TOMUS w/supp & disclosures) Retropubic versus transobturator midurethral slings for stress incontinence. N Eng J Med 2010;362:2066-2076.

Richter, Brubaker, Moalli, Boreham (UITN) - Factors associated with incontinence frequency in a surgical cohort of stress incontinent women. (2005)

Richter, Brubaker, Zimmern, Sirls (UITN). [Pop 482, 7 yr fu] Patient Related Factors Associates with Long-Term Urinary Continence After Burch Colposuspension and Pubovaginal Fascial Sling Surgeries. J Uro, Vol. 188, 485-489, August 2012

Rinne, et al. [Pop 265, 12 mo fu] A randomized trial comparing TVT with TVT-O: 12-month results. Int Urogynecol J (2008) 19:1049 1054

Rinne, Nilsson. [Pop 42] Dynamic MRI confirms support of the mid-urethra by TVT and TVT-O surgery for stress incontinence. Nordic Federation of Societies of Obstetrics and Gynecology 90 (2011) 629–635

Riva D, Sacca V, Tonta A, et al. [Pop 131, 1 yr fu] IUGA Abs. 060 - TVT versus TOT: a randomized study at 1 year follow-up. Int Urogynecol J 2006; 17 (Suppl 2): S57-S100

Rogers. Sexual function in women with pelvic floor disorders. (2013)

Rogers. What's Best in the Treatment of Stress Urinary Incontinence? (2010) 10.1056/nejme1005367

Rogo-Gupta L, et al. Trends in the Surgical Management of Stress Urinary Incontinence Among Female Medicare Beneficiaries, 2002-2007. Urology (2013)

Schimpf M. Sling surgery for stress urinary incontinence in women: a systematic review and metaanalysis. Am J Obstet Gynecol 2014 211(1): 1.e1-1.e27

Medical Literature

Schimpf MO, et al. "Sling Surgery for Stress Urinary Incontinence in Women: A Systematic Review and Metaanalysis", Schimpf MO, Rahn DD, Wheeler TL, et al. Sling surgery for stress urinary incontinence in women: a systematic review and metaanalysis. *Am J Obstet Gynecol 2014; 210.* 

Schiotz H. [Pop 33, 10 yr fu] Ten-year follow-up after conservative treatment of stress urinary incontinence. Int Urogynecol J (2008) 19:911-915

Schraffordt Koops. [Pop 634, 2 yr fu] Quality of life before and after TVT, a prospective multicentre cohort study, results from the Netherlands TVT database. BJOG 2006; 113:26–29

Schraffordt Koops. Result of the tension-free vaginal tape in patients with concomitant prolapse surgery: a 2-year follow-up study. An analysis from the Netherlands TVT database. Int Urogynecol J (2007) 18:437–442

Schraffordt. The effectiveness of tension-free vaginal tape (TVT) and quality of life measured in women with previous urogynecologic surgery: Analysis from The Netherlands TVT database. American Journal of Obstetrics and Gynecology (2006) 195~ 439-44

Seklehner S, et al. A Meta-analysis of the performance of retropubic midurethral slings vs. transobturator midurethral slings. The Journal of Urology, Vol. 193, 909-915, March 2015.

Serati M, Bauer R, Cornu JN, Cattoni E, Braga A, Siesto G, Lizée D, Haab F, Torella M, Salvatore S. [Pop 191, 5 yr fu] TVT-O for the treatment of pure urodynamic stress incontinence: efficacy, adverse effects, and prognostic factors at 5-year follow-up. Eur Urol (2013) 63:872-878

Serati M, Ghezzi F, Cattoni E, Braga A, Siesto G, Torella M, Cromi A, Vitobello D, Salvatore S. [Pop 58, but 10 yrs fu] Tension-free vaginal tape for the treatment of urodynamic stress incontinence: efficacy and adverse effects at 10-year follow-up. Eur Urol (2012) 61:939-946

Serati. Surgical treatment for female stress urinary incontinence: what is the gold-standard procedure? Int Urogynecol J (2009) 20:619–621

Seratti, M. TVT-O for the treatment of Pure Urodynamics Stress Incontinence: Efficacy, Adverse Efefcts, and Prognostic Factos at 5-years Follow-up. European Urology 63; 872-878 (2013)

Shah D, et al. (Sovrin) Impact of Vaginal Surgery for Stress Urinary Incontinence of Female Sexual Function; Is the Use of Polypropylene Mesh Detrimental? UROLOGY 65: 270–274, 2005

Shah. Surgical management of lower urinary mesh perforation after mid-urethral polypropylene mesh sling: mesh excision, urinary tract reconstruction and concomitant pubovaginal sling with autologous rectus fascia. (2013)

Shao. [Pop 24, median 57 mo fu] Tension-free vaginal tape retropubic sling for recurrent stress urinary incontinence after Burch colposuspension failure. International Journal of Urology (2011) 18, 452-457

Sharifiaghdas. [Pop 100, mean 40 mos fu] Tension-free vaginal tape and autologous rectus fascia pubovaginal sling for the treatment of urinary stress incontinence: a medium-term follow-up. Med Princ Pract 2008;17:209–214

Shin Y. [Pop 46, 2 yr fu] Efficacy and Safety of the TVT-Secur and Impact on Quality of Life in Women with Stress Urinary Incontinence: A 2-Year Follow-up. Korean J Urol 2011;52:335-339

Shippey S. Contemporary Approaches to Cystocele Repair: A Survey of AUGS Members. The Journal of Reproductive Medicine, 53:11 (Nov 2008).

Sobhgol. Rate and related factors of dyspareunia in reproductive age women: a cross-sectional study. International Journal of Impotence Research (2007) 19, 88–94

Sola V. [Pop 110, mean 8 mo fu] Third Generation Sub-Mid Urethral Mesh: Experience with 110 TVT-Secur. Arch. Esp. Urol. 2009; 62 (5): 376-388

Song. [Pop 306, 7 yr fu] The 7-year outcome of the tension-free vaginal tape procedure for treating female stress urinary incontinence. 2009 BJU INTERNATIONAL 104, 1113–1117

Stanford, Paraiso. A Comprehensive Review of Suburethral Sling Procedure Complications. Journal of Minimally Invasive Gynecology (2008) IS, 132- 145 © 2008

Stanton. Stress Incontinence: Why and How Operations Work. Urologic Clinics of North America, Vol. 12, No. 2, May 1985.

Summitt Bent Ostergard. Suburethral sling procedure for genuine stress incontinence and low urethral closure pressure. A continued experience. Int Urogynecol J (1992)3:18-21

Suskind AM, et al. Effectiveness of mesh compared with nonmesh sling surgery in Medicare beneficiaries. Obstet Gynecol. 2013 Sep;122(3):546-52.

Svenningsen R, et al. (Norwegian registry) [Pop 542, median 129 mo fu] Long-term follow-up of the retropubic tension-free vaginal tape procedure. Int Urogynecol J. 2013 Aug;24(8):1271-78

Svenningsen R. [Pop 810, 10 yr fu] Risk Factors for Long-Term Failure of the Retropubic Tension-Free Vaginal Tape Procedure. Neurourol. Urodynam, 2013 Wiley Periodicals.

Tamussino K. (Austrian registry) [Pop 2543] Transobturator tapes for stress urinary incontinence: Results of the Austrian registry. Am J Obstet Gynecol 2007;197:634.e1-634.e5.

Tamussino. (Austrian registry) [Pop 2795 - procedure-related cxs.] Tension-Free Vaginal Tape Operation: Results of the Austrian Registry. Obstet Gynecol, 98: 732–736, 2001

Tang X. [Pop 33, 12 mo fu] Short-Term Effect of TVT-Secure Procedure on Quality of Life and Sexual Function in Women with Stress Urinary Incontinence. Journal of Minimally Invasive Gynecology (2013) 20, 455–459

Tate A. The use of infection prevention practices in female pelvic medicine and reconstructive surgery. Curr (Teo R, Moran P, Mayne C, Tincello D. [Pop 127, 6 mo fu] Randomized trial of tension-free vaginal tape and tension-free vaginal tape-obturator for urodynamic stress incontinence in women. J Urol 2011;185:1350-1355.

Thunedborg. [Pop 36, 6-8 yr fu] Stress urinary incontinence and posterior bladder suspension defects. Acta Obstet Gynecol Scand 1990; 69: 55 - 59

Tincello D. The TVT Worldwide Observational Registry for Long-Term Data: Safety and Efficacy of Suburethral Sling Insertion Approaches for Stress Urinary Incontinence in Women. The Journal of Urology, Vol. 186, 2310-2315, December 2011

Tincello DG, Kenyon S, Slack M, et al. Colposuspension or TVT with anterior repair for urinary incontinence and prolapse: results of and lessons from a pilot randomised patient-preference study (CARPET 1). BJOG 2009;116:1809-1814.

Toglia, DeLancey. Anal incontinence and the obstetrician-gynecologist. Obstet Gynecol 1994;84:731-40

Tommaselli G. (EurJObGynRB) Efficacy of a modified technique for TVT-O positioning: a twelve-month, randomized, single-blind, multicenter, non-inferiority study. Eur J Obstet Gynecol (2012)

Tommaselli G. [Pop 68, 2 yr fu] TVT-Secur for the treatment of female stress urinary incontinence: a 24-month follow-up retrospective study. Arch Gynecol Obstet (2012) 286:415-421.

Tommaselli G. [Pop 78, 12 mo fu] IUGA Abs. 0692 - Comparison of TVT-O and TVT-Abbrevo for the surgical management of female stress urinary incontinence: a 12-months preliminary study. International Journal of Gynecology & Obstetrics 119S3 (2012) S261–S530

Tommaselli G. Tension-Free Vaginal Tape-O and -Secur for the Treatment of Stress Urinary Incontinence. A Thirty-Six-Month follow-up Single-blind Double-arm, Randomized study. Journal of Minimally Invasive Gynecology, Vol 20, No 2, March/April 2013.

Tommaselli GA, Di Carlo C, Gargano V, Formisano C, Scala M, Nappi C. [Pop 84, 12 mo fu] Efficacy and safety of TVT-O and TVT-Secur in the treatment of female stress urinary incontinence: 1-year follow-up. Int Urogynecol J (2010) 21:1211-1217

Tommaselli GA, et al. Mid-term and long-term outcomes following placement of midurethral slings for stress urinary incontinence: A systematic review and metaanalysis. *Int Urogynecol J 2015*.

Tommaselli. [Pop 48. 24 mo fu] IUGA,ICS Abs 791 Single incision tension-free vaginal tape (TVT-Secur®) in the treatment of female stress urinary incontinence. (2010)

Trabuco E. Medium-term Comparison of continence rates after rectus fascia or midurethral sling placement. Am J Obstet Gynecol 2009; 200:300.e1-300.e6

Trabuco E. Midurethral Slings for the Treatment of Stress Urinary Incontinence: Long-Term Follow-up. (2014)

Trabuco, E. A randomized comparison of incontinence procedures performed concomitantly with abdominal sacral colpopexy: the burch versus mid-urethral sling trial. Int Urogynecol J (2014) 25 (Suppl 1):S1-S240.

Tseng LH, Wang AC, Lin Y-H, Li S-J, Ko Y-J. [Pop 62] Randomized comparison of the suprapubic arc sling procedure vs tension-free vaginal taping for stress incontinent women. Int Urogynecol J Pelvic Floor Dysfunct 2005;16:230-235.

UITN Investigators. The Trial Of Mid-Urethral Slings (TOMUS): Design and Methodology. The Journal of Applied Research • Vol. 8, No. 1, 2008

Ulmsten A. [Pop 50, 3 yr fu] A three-year follow up of tension free vaginal tape for surgical treatment of female stress urinary incontinence. British Journal of Obstetrics and Gyneccology April 1999, Vol 106, pp. 345-350

Ulmsten U, et al. (TVT Treatise) [Pop 75, 2 yr fu] An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. Int Urogynecol J (1996) 7:81-86.

Ulmsten U, et al. [Pop 131, 1 yr fu] A multicenter study of tension-free vaginal tape (TVT) for surgical treatment of stress urinary incontinence. Int Urogynecol J (1998) 9:210-213

Ulmsten U, et al. Different biochemical composition of connective tissue in continent and stress incontinent women. Acta Obstet Gynecol Scand 66:455-457, 1987.

Ulmsten U, et al. Intravaginal Slingplasty (IVS) - an Ambulatory Surgical Procedure for Treatment of Female Urinary Incontinence. Scand J Urol Nephrol 29: 75-82, 1995.

Ulmsten U. [Editorial on Nilsson] An Introduction to Tension Free Vaginal Tape (TVT) - A New Surgical Procedure for Treatment of Female Urinary Incontinence. Int Urogynecol J (2001) (Suppl 2):S3-S4

Ulmsten U. The basic understanding and clinical results of tension-free vaginal tape for stress urinary incontinence. Urologe [A] 2001 - 40:269-273.

Unger CA, et al. [Pop 267] Indications and risk factors for midurethral sling revision. In Urogynecol J (2015)

Usher. Use of Marlex Mesh in the repair of incisional hernias. (1958)

Ustun Y, Engin-Ustun Y, Gungor M, Tezcan S. [Pop 46, 18 mo fu] Tension-free vaginal tape compared with laparoscopic Burch urethropexy. J Am Assoc Gynecol Laparosc 2003;10:386-389.

Valpas A, Kivela A, Penttinen J, Kujansuu E, Haarala M, Nilsson C-G. [Pop 121, 1 yr fu - Ob Gyn] Tension-free vaginal tape and laparoscopic mesh colposuspension for stress urinary incontinence. Obstet Gynecol 2004;104:42-49.

Valpas, Nilsson. [Pop 121, 5 yr fu] TVT versus laparoscopic mesh colposuspension: 5-year follow-up results of a randomized clinical trial. Int Urogynecol J (2014)

van Geelen. [Pop 90, 5-7 yr fu] The clinical and urodynamic effects of anterior vaginal repair and Burch colposuspension. Am J Obstet Gynecol 1988;159:137-44.

Vervest. [Pop 703, 36 mo fu] The prevalence of voiding difficulty after TVT, its impact on quality of life, and related risk factors. Int Urogynecol J (2007) 18: 173–182

Wadie BS, Edwan A, Nabeeh AM. [Pop 53, 6 mo fu] Autologous fascial sling vs polypropylene tape at short-term followup: a prospective randomized study. J Urol 2005;174:990-993.

Wadie BS, Mansour A, El-Hefnawy AS, Nabeeh A, Khair AA. Minimum 2-year follow-up of mid-urethral slings, effect on quality of life, incontinence impact and sexual function. Int Urogynecol J 2010;21:1485-1490.

Wai, Sirls. (UITN TOMUS) Patient Satisfaction After Midurethral Sling Surgery for Stress Urinary Incontinence. Obstet Gynecol 2013;121:1009–16

Wai. Surgical Treatment for Stress and Urge Urinary Incontinence. Obstet Gynecol Clin N Am 36 (2009) 509–519

Walsh C. [Pop 1178, 12 mo fu] TVT-Secur mini-sling for stress urinary incontinence: a review of outcomes at 12 months. BJU International (2011), 108, 652-657

Walters, Weber. [OBMgmt] Which sling for which SUI patient? OBG Management, Vol 24, No. 5, May 2012

Waltregny, de Leval. Inside Out Transobturator Vaginal Tape for the Treatment of Female Stress Urinary Incontinence: Interim Results of a Prospective Study After a 1-Year Minimum Followup (2006) [ETH.MESH.3939167-71]

Waltregny, de Leval. New surgical technique for treatment of stress urinary incontinence TVT-ABBREVO from development to clinical experience. Surg Technol Int (2012) 22:149-157

Wang -[Pop 503] Burch colposuspension vs. Stamey bladder neck suspension: A comparison of complications with special emphasis on detrusor instabiligy and voiding dysfunction. J Reprod Med 1996; 41:529-533

Wang AC, Chen M-C. [Pop 90, median 22 mo fu] Comparison of tension-free vaginal taping versus modified Burch colposuspension on urethral obstruction: a randomized controlled trial. Neurourol Urodyn. 2003;22(3):185-190.

Wang F, Song Y, Huang H. [Pop 140] Prospective randomized trial of TVT and TOT as primary treatment for female stress urinary incontinence with or without pelvic organ prolapse in Southeast China. Arch Gynecol Obstet 2010;281:279-286.

Wang W, Zhu L, Lang J. [Pop 300, 36 mo fu] Transobturator tape procedure versus tension-free vaginal tape for treatment of stress urinary incontinence. Int J Gynaecol Obstet 2009;104:113-116.

Wang. [Pop 102, 1 yr fu] Comparison of three mid-urethral tension-free tapes (TVT, TVT-O, and TVT-Secur) in the treatment of female stress urinary incontinence: 1-year follow-up. Int Urogynecol J (2011) 22: 369-374

Ward K, et al. (BMJ) [IRELAND] Prospective multicentre randomised trial of tension-free vaginal tape and colposuspension as a primary treatment for stress incontinence. bmj.com 2002;325:67

Ward, Hilton. (BJOG) [Pop 344, 5 yr f\_u IRELAND study] Tension-free vaginal tape versus colposuspension for primary urodynamic stress incontinence: 5-year follow up. BJOG 2008;115:226–233

Case 2:12-md-02327 Document 2046-4 Filed 04/21/16 Page 26 of 37 PageID #: 39400 Bergmann, Cynthia - Materials List, updated 2.29.16.XLSX Medical Literature

Ward. (Am J OG) [Pop 344, 2 yr. fu IRELAND study] A Prospective multicentre randomised trial of tension-free vaginal tape and colposuspension for primary urodynamic stress incontinence: Two-year follow-up. American Journal of Obstetrics and Gynecology (2004) 190, 324-31

Weber A. Which Slings for which SUI Patient? OBG Management, Vol. 24, No. 5, May 2012

Weinberger, Ostergard. Long-Term Clinical and Urodynamic Evaluation of the Polytetrafluoroethylene Suburethral Sling for Treatment of Genuine Stress Incontinence. Obstet Gynecol 1995;86:92-6

Welk B, et al. Removal or Revision of Vaginal Mesh Used for the Treatment of Stress Urinary Incontinence. JAMA Surg. 2015

Wilson. Annual direct cost of urinary incontinence. Obstet Gynecol 2001;98:398-406

Winters Urology Care. A Conversation with Dr. Winters: Question About "Vaginal Mesh" for SUI Repair. (2014)

Withagen. [Pop 186 (Prolift 83), 1 yr fu] Trocar-Guided Mesh compared With Conventional Vaginal Repair in Recurrent Prolapse. Obstet Gynecol 2011;117:242–50

Wu C-J, et al. The surgical trends and time-frame comparison of primary surgery for stress urinary incontinence, 2006-2010 vs 1997-2005: a population-based nation-wide follow-up descriptive study. Int Urogynecol J (2014) 25:1683-1691

Wu J. Forecasting the Prevalence of Pelvic Floor Disorders in U.S. women 2010 to 2050. Obstetrics and Gynecology, 114:6, Dec 2009.

Wu JM, et al. [Pop 907] Prevalence and incidence of urinary incontinence in a diverse population of women with noncancerous gynecologic conditions. Female Pelvic Med Reconstr Surg. 2010; 16(5):284-289.

Wu JM, et al. Predicting the number of women who will undergo incontinence and prolapse surgery, 2010 to 2050. Am J Obstet Gynecol 2011 September; 205(3):230.e1-230.e5

Wu JM, et al. Trends in inpatient urinary incontinence surgery in the USA, 1998-2007. Int Urogynecol J (2011) 22:1437-1443.

Zhang Y, Jiang M, Tong X-W, Fan B-Z, Li H-F, Chen X-L. The comparison of an inexpensive-modified transobturator vaginal tape versus TVT-0 procedure for the surgical treatment of female stress urinary incontinence. Taiwan J Obstet Gynecol 2011;50:318-321.

Zhu L, Lang J, Hai N, Wong F. [Pop 56, mean of 27.6 mo fu] Comparing vaginal tape and transobturator tape for the treatment of mild and moderate stress incontinence. Int J Gynaecol Obstet 2007;99:14-17.

Zoorob D. Management of Mesh Complications and Vaginal Constriction: A urogynecology Perspective. Urol Clin N Am 2012; 39: 413-418.

Zullo MA, Plotti F, Calcagno M, et al. Eur Urol One-year follow-up of tension-free vaginal tape (TVT) and Transobturator suburethral tape from inside to outside (TVT-0) for surgical treatment of female stress urinary incontinence: a prospective randomised trial. Eur Urol 2007;51:1376-1382; discussion 1383-1384.

Zyczynksi HM, et al. Sexual Activity and Function in Women more than 2 Years after Midurethral Sling Placement. *Am J Obstet Gynecol 2012; 207:421.e1-6.* 

Case 2:12-md-02327 Document 2046-4 Filed 04/21/16 Page 27 of 37 PageID #: 39401 Berggmann, Cynthia - Materials List, updated 2.29.16.XLSX

**Production Materials** 

01/28/98 Letter from FDA re: K974098 TVT System [ETH.MESH.371496-594]

05/13/2003 Memo to Gynecare Continence Health Sales Team re: Gynecare TVT Physician Training Policy [ETH.MESH.7393700]

09/07/2009 Safety review: TVT and TVT-O procedures [ETH.MESH.1751069-94]

10/12/1990 Letter from FDA re: N16374, Prolene Polypropylene Nonabsorbable Suture

11/11/10 Letter from John Young re: Global Regulatory Strategy for TVT IFU (RMCP15506/E) Update (Part II, RA0001-2010, Rev. 1) [ETH.MESH.341006-11]

12/15/2003, Gynecare Final Report # 03\*0740, TVT Obturator System [ETH.MESH.222852-63]

2000 June TVT Surgeons Resource Monograph

2006 Apr 19 - Laser Cut Mesh for Gynecare TVT- CER Laser Cut Mesh [ETH.MESH.00167104 -10]

2006 Mar 3 Flatow memo - CPC-2006-0165 Performance evaluation of TVT PROLENE blue Mesh\_ Elongation Properties of Mechanical Cut verses Laser Cut

Application FMEA for TVT Classic Doc# FMEA-0000536 Rev.<1>

Clinical Evaluation Report, Gynecare TVT Tension-free Vaginal Tape / Tension-free Vaginal Tape Accessory Abdominal Guide [ETH.MESH.4384126-65]

Clinical Expert Report [ETH.MESH.1784823-28]

Clinical Expert Report [ETH.MESH.222899-909]

Corporate Product Characterization Plan, TVT-Laser Cut Mesh. Dated 02/06/2006

De Leval (2003) Novel SurgicalTechnique for theTreatment of Female Stress Urinary Incontinence:

Transobturator Vaginal Tape Inside-Out

Email from Arnaud re: Transient Leg Pain with Mulberry [ETH.MESH.3911390-1]

Email from Dan Smith re: Draft report translated by "Babel fish" http://babelfish.altavista.com/tr [ETH.MESH.865069-72]

Email from Dan Smith re: NG TVT-O NDP – Outcomes from Kickoff Meeting with Pr. De Leval & Dr. Waltregny [ETH.MESH.2293715-6]

Email from Hinoul re: South Africa, TVTO sheaths getting stuck upon removal [ETH.MESH.1210987-95]

Email from O'Bryan re: GYNECARE TVT Obturator System - FDA [ETH.MESH.6882641-2]

Email from O'Bryan re: ifu [ETH.MESH.3364663-66]

Email from Seppa re: Performance Evaluation of TVT Secur PROLENE Mesh: Mechanical vs. Laser Cut. Study (LIMS #BE-2004-1920)

Email from Seppa re: Performance Evaluation of TVT U PROLENE Mesh: Mechanical vs. Laser Cut. Study (LIMS #BE-2004-1920) Version 2

Email from Weisberg re: IFU update [ETH.MESH.3365250-1]

Email from Weisberg re: Mulberry [ETH.MESH.6886410-11]

Email re: Important Laser cut mesh update [ETH.MESH.1809056-58]

Email re: Laser Cut TVT [ETH.MESH.6859834-35]

Email re: Mesh Fraying Dr. EBERHARD letter [ETH.MESH.7692905-7]

Email re: OR Agenda Tunn [ETH.MESH.3922926-28]

Email re: Performance Evaluation of TVT Prolene Blue Mesh [ETH.MESH.6696411-19]

Email re: TVT Laser Cut Mesh [ETH.MESH.525573]

Email re: TVT Laser Mesh info [ETH.MESH.442825-26]

Email re: TVT Meeting with Agency [ETH.MESH.524746-48]

ETH.MESH.00144270-78

ETH.MESH.00160615-25

ETH.MESH.00295355

ETH.MESH.00369995

**Production Materials** 

ETH.MESH.00373310-88		
ETH.MESH.00397674		
ETH.MESH.00442129		
ETH.MESH.00584811-13		
ETH.MESH.00658421-29		
ETH.MESH.00993273		
ETH.MESH.01320328-33		
ETH.MESH.01320351-67		
ETH.MESH.01613143-46		
ETH.MESH.02248778 - Mechanical vs Machine Cut (Laser.Ultrasonic) Mesh Particle loss less than 2 percent for		
both		
ETH.MESH.02340471-503		
ETH.MESH.02340504-67		
ETH.MESH.02614610-624		
ETH.MESH.03427878-945		
ETH.MESH.03458123-38		
ETH.MESH.03459088-104		
ETH.MESH.03459088-104		
ETH.MESH.03751819		
ETH.MESH.03905968-975		
ETH.MESH.03905976-991		
ETH.MESH.03905992-6000		
ETH.MESH.03906037-052		
ETH.MESH.03932912-14		
ETH.MESH.04939001		
ETH.MESH.05222673-705		
ETH.MESH.052235354-85		
ETH.MESH.05225354-85		
ETH.MESH.05795421-508		
ETH.MESH.05795537-99		
ETH.MESH.06087471-2		
ETH.MESH.06087513-4		
ETH.MESH.07246690-719		
ETH.MESH.07351297		
ETH.MESH.08003173-80		
ETH.MESH.08003181-96		
ETH.MESH.08003197-212		
ETH.MESH.08003215-30		
ETH.MESH.08003231-46		
ETH.MESH.08003247-62		
ETH.MESH.08003263-78		
ETH.MESH.08003279-94		
ETH.MESH.08107354		
ETH.MESH.08117473		
ETH.MESH.08156958		
ETH.MESH.09744840-45		
ETH.MESH.09744848-55		

**Production Materials** 

- Troduction Materials
ETH.MESH.09744858-63
ETH.MESH.10220659
ETH.MESH.10281860-874
ETH.MESH.1210987-95
ETH.MESH.1222075-79
ETH.MESH.161953-54
ETH.MESH.1751069-94
ETH.MESH.1784779-82
ETH.MESH.1784823-28
ETH.MESH.1809056-58
ETH.MESH.1809080-81
ETH.MESH.1815660-64
ETH.MESH.19804279-86
ETH.MESH.222852-63
ETH.MESH.222899-909
ETH.MESH.2236604-09
ETH.MESH.223779-84
ETH.MESH.2293715-6
ETH.MESH.2340504-33
ETH.MESH.2340902-8
ETH.MESH.262089-123
ETH.MESH.3364663-66
ETH.MESH.3365250-1
ETH.MESH.341006-11
ETH.MESH.3427878-83
ETH.MESH.371496-594
ETH.MESH.3922926-28
ETH.MESH.3932909-11
ETH.MESH.3934952-67
ETH.MESH.4048515-20
ETH.MESH.4384126-65
ETH.MESH.442825-26
ETH.MESH.524746-48
ETH.MESH.525573
ETH.MESH.5315252-65
ETH.MESH.658177-658198
ETH.MESH.6696411-19
ETH.MESH.6859834-35
ETH.MESH.6878438-39
ETH.MESH.6882641-2
ETH.MESH.6886410-11
ETH.MESH.7393700
ETH.MESH.7692905-7
ETH.MESH.8003295-301
ETH.MESH.8003303-17
ETH.MESH.823793-806
ETH.MESH.865069-72

Case 2:12-md-02327 Document 2046-4 Filed 04/21/16 Page 30 of 37 PageID #: 39404 Berggmann, Cynthia - Materials List, updated 2.29.16.XLSX

**Production Materials** 

ETH.MESH.PM.000006 ETH.MESH.PM.000009

ETH.MESH.PM.000057

ETH.MESH.PM.000068

ETH.MESH.PM.000088

ETH.MESH.PM.000089

ETH.MESH.PM.000090

ETH.MESH.PM.000134

ETH.MESH.PM.000151

ETH.MESH.PM.000154

Final Report, PSE Accession No. 97-0197, Project No. 16672 [ETH.MESH.5315252-65]

Gynecare TVT Obturator System Sales Materials [ETH.MESH.161953-54]

Gynecare TVT Tension-free Support for Incontinence: Advanced Users Forum for the Experienced Clinician

Gynecare TVT Tension-free Support for Incontinence: Professional Education Slides

History of TVT-O [ETH.MESH.3932909-11]

KOL Interview [ETH.MESH.4048515-20]

Letter from Dr. Joerg L. Holste, re: Biocompatibility Risk Assessment for Laser-cut Implant of Gynecare TVT

Letter to Weisberg/Robinson re: Elongation Characteristics of Laster Cut PROLENE Mesh for TVT, from Kammerer [ETH.MESH.1222075-79]

Manuscript Draft: (de Leval) Novel surgical technique for the treatment of female stress urinary incontinence:

Transobturator Vaginal Tape Inside-Out [ETH.MESH.262089-123]

Memo from Kammerer/ Silimkhan re: Ultrasonic Slitting of PROLENE Mesh for TVT

Memo re: Comparison of Laser-cut and machine-cut TVT Mesh to Meshes from Competetive Devices (BE02004-1641) [ETH.MESH.1809080-81]

Memo re: TVT-Base & TVT-O Complaint Review for Laser Cut Mesh (LCM) Risk Analysis [ETH.MESH.1784779-82]

Memo re: VOC on new Laser Cut TVT Mesh [ETH.MESH.6878438-39]

Patient Brochure: "Stop coping, start living." [ETH.MESH.8003295-301]

Patient Brochure: "Stop coping, start living." [ETH.MESH.8003303-17]

PowerPoint Mechanical vs. "Machine"-cut Mesh, January 19, 2005 Prepared by: Allison London Brown & Gene Kammerer

Project Mulberry, Preliminary Clinical Diligence Report [ETH.MESH.1815660-64]

Risk Management Report, TVT Laser Cut Mesh (LCM). Document Number RMR0000017, Rev. 3 [ETH.MESH.223779-84]

Surgeon's Resource Monograph, A Report of the June 2000 Summit Meeting [ETH.MESH.658177-658198]

Tension-Free Vaginal Obturator Tape (TVOT) – April 30, 2003 – Meeting Report [ETH.MESH.3934952-67]

The History of TVT

Transobturator Vaginal Tape Inside-Out (TVT-O): From Development to Clinical Experience [ETH.MESH.823793-806]

TVT IFU [ETH.MESH.2340504-33]

TVT IFU [ETH.MESH.3427878-83]

TVT O IFU [ETH.MESH.2340902-8]

TVT Obturator Brochure; "Results, Precision & Proven Mesh" [ETH.MESH.2236604-09]

Case 2:12-md-02327 Document 2046-4 Filed 04/21/16 Page 31 of 37 PageID #: 39405 Berggmann, Cynthia - Materials List, updated 2.29.16.XLSX Production Materials

TVT Surgeons Resource Monograph - June 2000 [ETH.MESH.10027307-28]
Waltregny (2006) Inside Out Transobturator Vaginal Tape for the Treatment of Female Stress Urinary
Incontinence: Interim Results of a Prospective Study After a 1-Year Minimum Followup [ETH.MESH.3939167-
71]

Case 2:12-md-02327 Document 2046-4 Filed 04/21/16 Page 33 of 37 PageID #: 39407 Bergmann, Cynthia - Materials List, updated 2.29.16.XLSX

Other Materials

### **Publically Available**

01/28/98 Letter from FDA re: K974098 TVT System [ETH.MESH.371496-594]

05/13/2003 Memo to Gynecare Continence Health Sales Team re: Gynecare TVT Physician Training Policy [ETH.MESH.7393700]

09/07/2009 Safety review: TVT and TVT-O procedures [ETH.MESH.1751069-94]

10/12/1990 Letter from FDA re: N16374, Prolene Polypropylene Nonabsorbable Suture

11/11/10 Letter from John Young re: Global Regulatory Strategy for TVT IFU (RMC P15506/E) Update (Part II, RA0001-2010, Rev. 1) [ETH.MESH.341006-11]

12/15/2003, Gynecare Final Report # 03\*0740, TVT Obturator System [ETH.MESH.222852-63]

2009 AUA Guideline for the Surgical Management of Female Stress Urinary I

2010 AUA Update of Guideline on the Surgical Management of Female Stress Urinary I

2011 AUA Foundation - Stress Urinary Incontinenc

2011 AUA Foundation - Stress Urinary Incontinence Monograph

2011 ICS Fact Sheet on Stress Urinary Incontinence

2011-Nov. AUA Position Statement on the Use of Vaginal Mesh for the Surgical Treatment of Stress Urinary I

2012 Update of AUA SUI Guidelines- Appendices A11 and A16 (re Complications)

2013 AUA Position Statement on the Use of Vaginal mesh for the Surgical Treatment of Stress Urinary Incontinence

2013 AUA SUI Patient Guide: 1 in 3 women experience Stress Urinary Incontinence

2013 AUGS Position Statement on Restriction of Surgical Options for Pelvic Floo

2013 FDA Condsierations about surgical mesh for SUI

2013 ICS Factsheets - SUI - p13 Miduretheral sling the choice

2013 March - AUGS Position Statement on Restrictions of Surgical Options for PFD FINAL

2013 Revised AUA Position Statement on the Use of Vaginal mesh for the Surgical Treatment of Stress Urinary Incontinence.

2013 Sept. NICE Guideline - Urinary Incontinence: The management of urinary incontinence in women. Issued September 2013.

2014 ACOG/AUGS Committee Opinion No 603 - Evaluation of uncomplicated SUI in women before surgical treatment. 2014

2014 AUGS FAQ by Providers MUS

2014 AUGS-SUFU MUS Position Statement APPROVED

2014 IUGA Position Statement regarding MUS for SUI

2014 Jan - AUGS-SUFU MUS Position Statement APPROVED 1 3 2014

2014 July - IUGA Position Statement on Mid-Urethral Slings for Stress Urinary Incontinence

2014 June - Joint ACOG-AUGS Position Statement on uncomplicated Stress Urinary Incontinence - CO 603

2014 Mar 12 - AUGS SUFU Provider FAQs MUS for SUI

2015 ACOG Practice Bulletin Summary of 155 - Urinary Incontinence in Women (replaces 63 from June 2005)

2015 ACOG, AUGS Practice Bulletin 155 (replaces 63 from 2005) Urinary Incontinence in Women

ACOG Practice Bulletin 63 (Obstet Gyn) Clinical Mgmt Guidelines for Ob-Gyns. Urinary Incontinence in Women. (2005)

Application FMEA for TVT Classic Doc# FMEA-0000536 Rev.<1>

**AUA-SUI Pocket Guide for Physicians** 

Clinical Evaluation Report, Gynecare TVT Tension-free Vaginal Tape / Tension-free Vaginal Tape Accessory Abdominal Guide [ETH.MESH.4384126-65]

Other Materials

Clinical Expert Report [ETH.MESH.1784823-28]

Clinical Expert Report [ETH.MESH.222899-909]

Corporate Product Characterization Plan, TVT-Laser Cut Mesh. Dated 02/06/2006.

De Leval (2003) Novel Surgical Technique for the Treatment of Female Stress Urinary Incontinence:

Transobturator Vaginal Tape Inside-Out

Email from Arnaud re: Transient Leg Pain with Mulberry [ETH.MESH.3911390-1]

Email from Dan Smith re: Draft report translated by "Babel fish" http://babelfish.altavista.com/tr [ETH.MESH.865069-72]

Email from Dan Smith re: NG TVT-O NDP – Outcomes from Kickoff Meeting with Pr. De Leval & Dr. Waltregny [ETH.MESH.2293715-6]

Email from Hinoul re: South Africa, TVTO sheaths getting stuck upon removal [ETH.MESH.1210987-95]

Email from O'Bryan re: GYNECARE TVT Obturator System - FDA [ETH.MESH.6882641-2]

Email from O'Bryan re: ifu [ETH.MESH.3364663-66]

Email from Seppa re: Performance Evaluation of TVT Secur PROLENE Mesh: Mechanical vs. Laser Cut. Study (LIMS #BE-2004-1920)

Email from Seppa re: Performance Evaluation of TVT U PROLENE Mesh: Mechanical vs. Laser Cut. Study (LIMS #BE-2004-1920) Version 2

Email from Weisberg re: IFU update [ETH.MESH.3365250-1]

Email from Weisberg re: Mulberry [ETH.MESH.6886410-11]

Email re: Important Laser cut mesh update [ETH.MESH.1809056-58]

Email re: Laser Cut TVT [ETH.MESH.6859834-35]

Email re: Mesh Fraying Dr. EBERHARD letter [ETH.MESH.7692905-7]

Email re: OR Agenda Tunn [ETH.MESH.3922926-28]

Email re: Performance Evaluation of TVT Prolene Blue Mesh [ETH.MESH.6696411-19]

Email re: TVT Laser Cut Mesh [ETH.MESH.525573]

Email re: TVT Laser Mesh info [ETH.MESH.442825-26]

Email re: TVT Meeting with Agency [ETH.MESH.524746-48]

FDA 2013 Mar - Considerations about Surgical Mesh for SUI

FDA Public Health Notification - 2008 Oct. 20

FDA Public Health Notification - 2011 July 11

FDA-Device Labeling Guidance #G91-1 (March 1991)

Final Report, PSE Accession No. 97-0197, Project No. 16672 [ETH.MESH.5315252-65]

Gynecare TVT Obturator System Sales Materials [ETH.MESH.161953-54]

Gynecare TVT Tension-free Support for Incontinence: Advanced Users Forum for the Experienced Clinician

Gynecare TVT Tension-free Support for Incontinence: Professional Education Slides

History of TVT-O [ETH.MESH.3932909-11]

http\_\_\_www.voicesforpfd - AUGS Patient Information: Mesh Information for Patients with Pelivic Floor Disorders

IUGA "Position Statement on Mid-Urethral Slings for Stress Urinary Incontinence", (2014)

(https://c.ymcdn.com/sites/www.iuga.org/resource/resmgr/Docs/midurethral\_slings3.pdf)

KOL Interview [ETH.MESH.4048515-20]

Letter from Dr. Joerg L. Holste, re: Biocompatibility Risk Assessment for Laser-cut Implant of Gynecare TVT

Letter to Weisberg/Robinson re: Elongation Characteristics of Laster Cut PROLENE Mesh for TVT, from Kammerer [ETH.MESH.1222075-79]

Case 2:12-md-02327 Document 2046-4 Filed 04/21/16 Page 35 of 37 PageID #: 39409 Bergmann, Cynthia - Materials List, updated 2.29.16.XLSX

Other Materials

Manuscript Draft: (de Leval) Novel surgical technique for the treatment of female stress urinary incontinence:

Transobturator Vaginal Tape Inside-Out [ETH.MESH.262089-123]

Memo from Kammerer/ Silimkhan re: Ultrasonic Slitting of PROLENE Mesh for TVT

Memo re: Comparison of Laser-cut and machine-cut TVT Mesh to Meshes from Competetive Devices (BE02004-1641) [ETH.MESH.1809080-81]

Memo re: TVT-Base & TVT-O Complaint Review for Laser Cut Mesh (LCM) Risk Analysis [ETH.MESH.1784779-82]

Memo re: VOC on new Laser Cut TVT Mesh [ETH.MESH.6878438-39]

Patient Brochure: "Stop coping, start living." [ETH.MESH.8003295-301]

Patient Brochure: "Stop coping, start living." [ETH.MESH.8003303-17]

PowerPoint Mechanical vs. "Machine"-cut Mesh, January 19, 2005 Prepared by: Allison London Brown & Gene Kammerer

Project Mulberry, Preliminary Clinical Diligence Report [ETH.MESH.1815660-64]

Risk Management Report, TVT Laser Cut Mesh (LCM). Document Number RMR-0000017, Rev. 3 [ETH.MESH.223779-84]

Surgeon's Resource Monograph, A Report of the June 2000 Summit Meeting [ETH.MESH.658177-658198]

Tension-Free Vaginal Obturator Tape (TVOT) – April 30, 2003 – Meeting Report [ETH.MESH.3934952-67]

The History of TVT

Transobturator Vaginal Tape Inside-Out (TVT-O): From Development to Clinical Experience [ETH.MESH.823793-806]

TVT & TVT-O Long Term Studies No Highlights - No Confidential Stamp

TVT IFU [ETH.MESH.2340504-33]

TVT IFU [ETH.MESH.3427878-83]

TVT O IFU [ETH.MESH.2340902-8]

TVT Obturator Brochure; "Results, Precision & Proven Mesh" [ETH.MESH.2236604-09]

Update AUA (2012) -SUI Guideline for the Surgical Management of Female Stress Urinary Incontinence: 2009 Update - Appendices A11 and A16 (re Complications)

FDA "Considerations about Surgical Mesh for SUI", (2013)

(http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGynSurgical Mesh/ucm345219.htm)

FDA "FDA Public Health Notifications: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence", (2008)

(http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm061976.htm)

FDA "UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse: FDA Safety Communication",

(2011)(http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm)

AUA "AUA Position Statement on the Use of Vaginal Mesh for the Surgical Treatment of Stress Urinary Incontinence" (2013), (https://www.auanet.org/about/vaginal mesh- for-sui.cfm)

AUA "Physician / Health Care Provider Pocket Guide: Stress Urinary Incontinence", 2011 American Urological Association Foundation, Inc.

AUGS & SUFU "Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence", (http://www.sufuorg.com/docs/news/AUGS-SUFU-MUS-Position-Statement-APPROVED-1-3-2014.aspx)

Case 2:12-md-02327 Document 2046-4 Filed 04/21/16 Page 36 of 37 PageID #: 39410 Bergmann, Cynthia - Materials List, updated 2.29.16.XLSX Other Materials

AUGS "Position Statement on Restriction of Surgical Options for Pelvic Floor Disorders" (2013), (http://atra.org/sites/default/files/documents/Position%20Statement%20Surgical%20Options%20for%20PFDs% 20(1).pdf)

MDL 200 Wave 1

Expert Reports	
Blaivas, Jerry (TVT-O General Report) - 2.1.2016	
Blaivas, Jerry (TVT-R General Report) - 2.1.2016	
Elliott, Daniel (TVT General Report) - 2.1.2016	
lakovlev, Vladimir (General) - 1.29.2016	
Margolis, Michael Thomas (TVT General Report) - 2.1.2016	